IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

	)	**REDACTED PUBLIC VERSION**
	)	
IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	Civil Action No. 05-356-SLR
	)	(consolidated)
	)	

JOINT PRETRIAL ORDER

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Dated: April 10, 2007

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On April 18, 2007, at 3:00 p.m., counsel for Plaintiffs Janssen Pharmaceutica N.V, Janssen L.P., and Synaptech, Inc. (collectively "Plaintiffs") and counsel for Defendants Alphapharm Pty., Ltd., Barr Pharmaceuticals, Inc., and Barr Laboratories, Inc. (collectively, "Defendants") will participate in a pretrial conference before this Court pursuant to Rule 16 of the Federal Rules of Civil Procedure and Rule 16.4 of this Court. A trial will be held on the claims and defenses in this action during specific dates to be set by the Court, commencing on or after May 21, 2007. The following matters as to trial of those claims are hereby Ordered by the Court:

I. NATURE OF THE ACTION AND THE PLEADINGS

1. In this action, In re: '318 Patent Infringement Litigation, C.A. No. 05-356-SLR (consolidated), Plaintiffs allege that Defendants have infringed claims 1 and 4 of U.S. Patent No. 4,663,318 ("the '318 Patent") by the filing of Abbreviated New Drug Applications ("ANDAs") that seek regulatory approval to make and sell a generic version of Plaintiffs' RAZADYNE® product prior to the expiration of the '318 Patent.[1] Plaintiffs seek a judgment that Defendants infringe claims 1 and 4 of the '318 Patent and that the patent is not invalid, injunctive relief, and a finding of an exceptional case.

2. On December 2, 2005, Defendants stipulated that each of the commercial use or sale of the drug products described in their respective ANDAs infringes claims 1 and 4 of the '318 Patent if valid and enforceable; Plaintiffs stipulated that they only assert claims 1 and 4 of the '318 Patent. (D.I. 49.)

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[1] RAZADYNE® is a registered trademark, however, in this Joint Pretrial Order, the product will be identified without the trademark symbol. RAZADYNE® was previously marketed and sold under the tradename REMINYL®.

3. Defendants assert by way of their affirmative defenses and counterclaims that claims 1 and 4 of the '318 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and 112 for anticipation, obviousness, and/or lack of enablement. Defendants seek a judgment that the '318 Patent is invalid and a finding of an exceptional case.

4. The only issues remaining for trial are Defendants' defenses and counterclaims of patent invalidity, and the parties' respective claims of exceptional case.

The Patent

5. The patent-in-suit is U.S. Patent No. 4,663,318 ("the '318 Patent"). The application that led to the issuance of the '318 Patent was filed on January 15, 1986. The '318 Patent is titled "Method of Treating Alzheimer's Disease." The '318 Patent issued on May 5, 1987. Dr. Bonnie Davis is the inventor named on the '318 Patent. Synaptech, Inc. owns all right, title, and interest in the '318 Patent. The Janssen Plaintiffs have exclusive rights to the '318 Patent in the U.S., including the right to enforce the '318 Patent.

The Pleadings

6. On or before May 11, 2005, Alphapharm Pty, Ltd. ("Alphapharm") submitted to FDA an Abbreviated New Drug Application ("ANDA") (No. 77-603) and certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a so-called "Paragraph IV certification"), seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE® product before the expiration of the '318 Patent.

7. Plaintiffs sued Alphapharm for infringement of the '318 Patent on June 21, 2005, which was consolidated with the present action on October 21, 2005. (D.I. 31.) On August 11, 2005, Alphapharm filed an Answer and Counterclaim denying infringement of the '318 Patent, and alleging that the claims of the '318 Patent are invalid for failing to satisfy one or more of Sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code. Plaintiffs

filed their Reply to Alphapharm's Counterclaims on August 31, 2005, denying that the '318 Patent claims are invalid.

8. On or before May 13, 2005, Barr Laboratories, Inc., a wholly-owned subsidiary of Barr Pharmaceuticals, Inc. (collectively, "Barr") submitted to FDA an ANDA (No. 77-605) and Paragraph IV certification, seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product before the expiration of the '318 Patent.[2]

9. Plaintiffs sued Barr for infringement of the '318 Patent on June 10, 2005, which was consolidated with the present action on October 21, 2005. (D.I. 31.) On June 30, 2005, Barr filed an Answer, Affirmative Defenses, and Counterclaim denying infringement of the '318 Patent, and alleging that the claims of the '318 Patent are invalid for failing to satisfy one or more of Sections 101, 102, 103, and 112 of Title 35 of the United States Code. Plaintiffs filed their Reply to Barr's Counterclaims on July 19, 2005, denying that the '318 Patent claims are invalid.

10. On or before April 29, 2005, Dr. Reddy's Laboratories, Inc., a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's"), submitted to FDA an ANDA (No. 77-593) and Paragraph IV certification, seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product before the expiration of the '318 Patent.

11. Plaintiffs sued Dr. Reddy's for infringement of the '318 Patent on June 10, 2005, which was consolidated with the present action on October 21, 2005. (D.I. 31.) On

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[2] Plaintiffs also named Barr Pharmaceuticals, Inc., the parent of Barr Laboratories, Inc. (collectively, "Barr"), in their lawsuit. Barr has identified this as an issue in Defendants' "Miscellaneous Issues" section (Tab 13) of the Joint Pretrial Order and will bring this to the Court's attention during the Pretrial Conference on April 18, 2007.

August 23, 2005, Dr. Reddy's filed an Answer and Counterclaim denying infringement of the '318 Patent, and alleging that the claims of the '318 Patent are invalid for failing to satisfy one or more of Sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code. Plaintiffs filed their Reply to Dr. Reddy's Counterclaims on September 12, 2005, denying that the '318 Patent claims are invalid.

12. On or before April 27, 2005, Mylan Pharmaceuticals, Inc., a wholly-owned subsidiary of Mylan Laboratories, Inc. (collectively, "Mylan"), submitted to FDA an ANDA (No. 77-590) and Paragraph IV certification, seeking approval to manufacture, market, and sell of generic version of Plaintiffs' RAZADYNE product before the expiration of the '318 Patent.

13. Plaintiffs sued Mylan for infringement of the '318 Patent on June 7, 2005, which was consolidated with the present action on October 21, 2005. (D.I. 31.) On July 21, 2005, Mylan filed an Answer, Affirmative Defenses, and Counterclaim denying infringement of the '318 Patent, and alleging that the claims of the '318 Patent are invalid for failing to satisfy one or more sections of Title 35 of the United States Code. Plaintiffs filed their Reply to Mylan's Counterclaims on August 8, 2005, denying that the '318 Patent claims are invalid.

14. On or before May 17, 2005, Par Pharmaceutical, Inc. ("Par") submitted to FDA an ANDA (No. 77-604) and Paragraph IV certification, seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product before the expiration of the '318 Patent.

15. Plaintiffs sued Par for infringement of the '318 Patent on June 29, 2005, which was consolidated with the present action on October 21, 2005. (D.I. 31.) On July 19, 2005, Parr filed an Answer, Affirmative Defenses, and Counterclaim denying infringement of

the '318 Patent, and alleging that the claims of the '318 Patent are invalid for failing to satisfy one or more of Sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code. Plaintiffs filed their Reply to Par's Counterclaims on August 8, 2005, denying that the '318 Patent claims are invalid.

16. On or before April 29, 2005, Purepac Pharmaceutical, Inc., a wholly-owned subsidiary of Alpharma, Inc. ("Alpharma"), submitted to FDA an ANDA (No. 77-585) and Paragraph IV certification, seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product prior to the expiration of the '318 Patent.

17. Plaintiffs sued Purepac and Alpharma for infringement of the '318 Patent on June 10, 2005, which was consolidated with the present action on October 21, 2005. (D.I. 31.) On June 30, 2005, Purepac and Alpharma filed an Answer and Counterclaim denying infringement of the '318 Patent, and alleging that the claims of the '318 Patent are invalid for failing to satisfy one or more of Sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code. Plaintiffs filed their Reply to Purepac's and Alpharma's Counterclaims on July 19, 2005, denying that the '318 Patent claims are invalid.

18. In early 2006, the Actavis Group, a corporation organized under the laws of Iceland that conducts business in the State of Delaware, acquired the generic pharmaceutical business of Alpharma, including Alpharma's former subsidiary, Purepac.

19. After the acquisition by Actavis Group, Plaintiffs and Alpharma agreed to substitute Actavis Group for Alpharma for all purposes in this action. (D.I. 176.)

20. On or before April 22, 2005, Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. (collectively, "Teva"), submitted to FDA an ANDA (No. 77-587) and Paragraph IV certification, seeking approval to manufacture,

market, and sell a generic version of Plaintiffs' RAZADYNE product prior to the expiration of the '318 Patent.

21. Plaintiffs sued Teva for infringement of the '318 Patent on June 3, 2005. (D.I. 1.) On June 23, 2005, Teva filed an Answer and Counterclaims denying infringement of the '318 Patent, and alleging that the claims of the '318 Patent are invalid for failing to satisfy one or more of Sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code. (D.I. 4.) Plaintiffs filed their Reply to Teva's Counterclaims on July 13, 2005, denying that the '318 Patent claims are invalid. (D.I. 6.)

22. All seven cases were consolidated on October 21, 2005. (D.I. 31.)

23. As noted above, on December 2, 2005, Defendants stipulated that each of the commercial use or sale of the drug products described in ANDAs No. 77-585 (Purepac), No. 77-587 (Teva), No. 77-590 (Mylan), No. 77-593 (Dr. Reddy's), No. 77-603 (Alphapharm), No. 77-604 (Par), and No. 77-605 (Barr) infringes claims 1 and 4 of the '318 Patent if valid and enforceable. (D.I. 49.)

24. Par Pharmaceutical, Inc. withdrew its Paragraph IV certification in favor of a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) (a so-called "Paragraph III certification"), seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product only after the expiration of the '318 Patent. By virtue of its Paragraph III Certification, Par no longer challenges the validity or enforceability of the '318 Patent. (D.I. 174.) Judge Jordan dismissed without prejudice the case against Par on May 5, 2006. (D.I. 186.)

25. The proceedings against Purepac and Actavis Group have been stayed as of May 5, 2006. Purepac and Actavis Group have agreed to be bound by the decision of the trial court in this case. (D.I. 177.)

26. The proceedings against Dr. Reddy's have been stayed as of May 31, 2006. Dr. Reddy agreed to be bound by the decision of the trial court in this case. (D.I. 236.)

27. The proceedings against Mylan have been stayed as of June 19, 2006. Mylan agreed to be bound by the decision of the trial court in this case. (D.I. 258.)

28. The proceedings against Teva have been stayed as of July 20, 2006. Teva agreed to be bound by the decision of the trial court in this case. (D.I. 298.)

29. Barr and Alphapharm are the only Defendants remaining that are actively litigating this case.

Pending Motions

REDACTED

REDACTED

II. FEDERAL JURISDICTION

34. Plaintiff Janssen Pharmaceutica N.V., a wholly-owned subsidiary of Johnson & Johnson, is a corporation organized and existing under the laws of Belgium and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

35. Plaintiff Janssen, L.P., a wholly-owned subsidiary of Johnson & Johnson, is a limited partnership organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

36. Plaintiff Janssen Pharmaceutica N.V. and Plaintiff Janssen L.P. (collectively, "Janssen") have certain rights to the '318 Patent.

37. Plaintiff Synaptech, Inc. ("Synaptech") is a company organized and existing under the laws of the State of New York and has its principal place of business care of Schwartz & Salomon, P.C., 225 Broadway, New York, New York 10007.

38. Defendant Alphapharm Pty., Ltd. ("Alphapharm") is a corporation organized under the laws of Australia with a principal place of business at Chase Building 2, 1 Wentworth Park Road, Glebe NSW 2037 Australia. Alphapharm does not dispute jurisdiction in this case.

39. Defendant Barr Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at Two Quaker Road, P.O. Box 2900, Pomona, NY. Barr Laboratories, Inc. conducts business in the State of Delaware.

40. Defendant Barr Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677. Barr Pharmaceuticals, Inc. conducts business in the State of Delaware. Barr Laboratories, Inc. is a wholly-owned subsidiary of Defendant Barr Pharmaceuticals, Inc. (collectively, "Barr").

41. Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized under the laws of the State of New Jersey and has its principal place of business at 200 Somerset Corporate Blvd., 22 West, Building 2, 7th floor, Bridgewater, New Jersey 08807. Dr. Reddy 's Laboratories, Inc. admitted jurisdiction exists in this case.

42. Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India with a principal place of business in India. Dr. Reddy's Laboratories, Ltd. admitted jurisdiction exists in this case. Defendant Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Defendant Dr. Reddy's Laboratories Ltd. (collectively, "Dr. Reddy's").

43. Defendant Mylan Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Defendant Mylan Pharmaceuticals, Inc. admitted that it is subject to personal jurisdiction in this case.

44. Defendant Mylan Laboratories, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania and having its principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317. Defendant Mylan Laboratories, Inc. did not dispute personal jurisdiction in this case. Defendant Mylan Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Mylan Laboratories, Inc. (collectively, "Mylan").

45. Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at One Ram Ridge Road, Spring Valley, New York 10977. Defendant Par Pharmaceutical, Inc. conducts business in the State of Delaware.

46. Defendant Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware and conducts business in the State of Delaware. Defendant Par Pharmaceutical, Inc. is a wholly owned subsidiary of Defendant Par Pharmaceutical Companies, Inc.

47. Defendant Purepac Pharmaceutical Co. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 14 Commerce Drive, Suite 301, Cranford, New Jersey 07016. Defendant Purepac conducts business in the State of Delaware.

48. Defendant Alpharma, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at One Executive Drive, Fort Lee, New Jersey 07024. Defendant Alpharma conducts business in the State of Delaware. Defendant Purepac Pharmaceutical, Inc. is a wholly owned subsidiary of Defendant Alpharma, Inc. (collectively, "Purepac" or "Alpharma").

49. Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Defendant Teva Pharmaceuticals USA, Inc. did not dispute jurisdiction in this case.

50. Defendant Teva Pharmaceutical Industries Ltd. is a foreign corporation organized and existing under the laws of Israel with its principal place of business in Israel. Defendant Teva Pharmaceutical Industries Ltd. did not dispute jurisdiction in this case. Defendant Teva Pharmaceutical USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. (collectively, "Teva").

51. This action arises under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

52. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b). No party contests venue.

III. JOINT STATEMENT OF ADMITTED FACTS REQUIRING NO PROOF

53. The parties' Joint Statement of Admitted Facts Requiring No Proof is attached as Tab 1.

IV. THE PARTIES' STATEMENTS OF ISSUES OF FACT WHICH REMAIN TO BE LITIGATED

54. Plaintiffs' Statement of Issues of Fact Which Remain To Be Litigated is attached as Tab 2.

55. Defendants' Statement of Issues of Fact Which Remain To Be Litigated is attached as Tab 3.

V. THE PARTIES' STATEMENTS OF ISSUES OF LAW WHICH REMAIN TO BE LITIGATED

56. Plaintiffs' Statement of Issues of Law Which Remain To Be Litigated is attached as Tab 4.

57. Defendants' Statement of Issues of Law Which Remain To Be Litigated is attached as Tab 5.

VI. THE PARTIES' PRE-MARKED TRIAL EXHIBITS

58. Plaintiffs' list of exhibits it may offer at trial and Defendants' objections thereto is attached as Tab 6.

59. Defendants' list of exhibits it may offer at trial and Plaintiffs' objections thereto is attached as Tab 7.

60. As to the supplementation of the parties' trial exhibits, the parties are not in agreement. **[Plaintiffs' version:** The right of a party to supplement its exhibit list upon sufficient and reasonable notice to the opposing side is subject to three limitations: (a) such supplementation is limited to instances in which a party can demonstrate good cause for the supplementation (i.e., that the need to supplement could not have been anticipated), (b) any proposed additions to the exhibit list must be of documents that relate directly to the issues that the Court will decide, and (c) the reservation of the right to supplement does not imply a waiver of any party's right to object to any proposed exhibit on any grounds.]. **[Defendants' version:** The parties reserve the right to list additional trial exhibits in response to any exhibits that the opposing party may provide in its Trial Exhibit List and/or objections to their own exhibits. The parties may supplement their exhibit list upon sufficient and reasonable notice to the opposing parties. The parties further reserve the right to amend their exhibit lists based on any future Court rulings, including but not limited to any rulings on Motions in Limine.]

61. The parties will offer at trial one or more of the exhibits set forth in the attached exhibit lists. These lists will include the exhibit numbers to be used at trial and a description sufficient to identify the exhibits.

62. Each party may use an exhibit that is listed on the other party's exhibit list, to the same effect as though it were listed on its own exhibit list, subject to evidentiary objections. Any exhibit, once admitted, may be used equally by each party, subject to any limitations as to its admission.

63. The listing of a document on a party's exhibit list is not an admission that such document is relevant or admissible when offered by the opposing side for the purpose that the opposing side wishes to admit the document. Each party reserves the right to object to the relevance of any evidence offered by the other party, at the time such evidence is offered, in view of the specific context in which such evidence is offered.

64. Exhibits and Demonstratives To Be Used In Opening and/or Closing Argument: The parties shall exchange copies of exhibits, including any demonstrative exhibits, (in color, and on 8½" x 11" paper or larger) to be used in opening by 7:00 p.m. the night before the exhibits are to be used. The parties shall exchange copies of any exhibits, including demonstrative exhibits, to be used in closing within 2 hours of the close of trial the day before the closing arguments are to occur.

65. Exhibits and Demonstratives To Be Used During Direct Examination of Witnesses: The parties shall identify the witness(es) and exhibits to be offered during the direct examination of the witness [**Plaintiffs' version**: within 2 hours of the end of the trial day or at 7:00 p.m. the day before such direct examination is expected to take place, whichever is later (or at 7:00 p.m. the day before the trial begins for witnesses testifying on the first day of trial).]

[**Defendants' version:** at least 48 hours before the witness is proffered.] The parties shall also serve copies of the demonstrative exhibits to be used during direct examination of a witness within 2 hours of the end of the trial day or at 7:00 p.m. the day before such direct examination is expected to take place, whichever is later (or at 7:00 p.m. the day before the trial begins for witnesses testifying on the first day of trial). The parties shall serve copies (in color, and on 8½" x 11" paper or larger) of any exhibits to be used in direct examination at the time specified above. The notice provisions of this paragraph shall not apply to demonstrative exhibits created in the courtroom during testimony at trial or the enlargement, simple highlighting, ballooning or excerption of trial exhibits or of testimony. The party receiving identification of demonstrative exhibits shall inform the party identifying the exhibits of any objections to such demonstrative exhibits within 2 hours of receiving them, and the parties shall meet and confer as soon as possible thereafter to resolve such objections. Any disputes as to demonstrative exhibits shall be raised with the Court before trial resumes on the day of their anticipated use.

66. The parties have agreed that the demonstrative exhibits the parties intend to use at trial do not need to be included on their respective lists of trial exhibits.

67. The parties shall make available for inspection physical exhibits to be used at trial, labeled with the exhibit number, within two hours of the end of the trial day before the day such physical exhibits are anticipated to be introduced.

68. The parties agree that exhibits to be used or offered in evidence solely for impeachment need not be included on the lists of trial exhibits or disclosed in advance of being used or offered at trial.

VII. WITNESSES TO BE CALLED

69. The witnesses (fact and expert) Plaintiffs may call in person or by deposition at trial are listed at Tab 8.

70. The witnesses (fact and expert) Defendants may call in person or by deposition at trial are listed at Tab 9.

71. **[Plaintiffs' version**: The listing of a witness on a party's witness list does not require that party to call that witness to testify, either live or by deposition.] **[Defendants' version**: The listing of a witness on a party's witness list as someone who may testify live requires that party to make the witness available to testify live should its opponent so demand.]

72. **[Plaintiffs' version**: The parties' fact witness lists shall be a subset of the fact witnesses identified in the witness list exchanges dated February 2, 2007 and March 2, 2007, subject to the dispute about Barr's identification of Michael Rainer, which is the subject of motions practice, described above.] **[Defendants' version**: Defendants believe that this paragraph is unnecessary.]

73. The parties agree that they may be able to pare down their witness lists in view of rulings made by the Court subsequent to the submission of this Joint Pretrial Order. Accordingly, **[Plaintiffs' version**: the Defendants shall identify one day before they begin their case-in-chief the witnesses they intend to call live or by deposition and the order in which they are expected to testify the following day. After the opening day of testimony, the parties shall provide final confirmation of the witnesses who will testify within 2 hours of the end of the trial day before the day on which such witness shall be called to testify.] **[Defendants' version:** on April 23, 2007, the parties will exchange final witness lists (both fact and expert) specifying who they expect to testify live and who they expect to testify by deposition, and on May 14, 2007 (one week before trial), the parties will exchange a list of the final order of the witnesses to be called live at trial for its case-in-chief. The parties shall provide final confirmation of witnesses who will testify within 1 hour of the end of the trial day before the day on which such witness

shall be called to testify. Only slight modification of the final anticipated order should be permitted.]

74. For any witness testifying by deposition, the parties shall provide deposition designations no later than [**Plaintiffs' version:** 5:00 p.m. four days prior to the date on which such testimony is expected to be introduced] [**Defendants' version:** on May 2, the parties shall provide via email deposition designations for issues on which that party bears the burden of proof]. A party receiving such designations shall provide objections and counter-designations by [**Plaintiffs' version:** 5:00 p.m., three days before the anticipated use of the designated testimony] [**Defendants' version:** on May 9, 2007 via email]. Any objections to counter-designations, or further rebuttal/context designations, shall be made [**Plaintiffs' version:** by 7:00 p.m. two days before the anticipated use of the designated testimony] [**Defendants' version:** May 16, 2007, via email]. The parties shall meet and confer within 1 day of receiving the final objections to counter-designations and further rebuttal/context designations in an attempt to resolve any objections.

75. Unless the Court prefers to proceed otherwise, with respect to deposition designations, counter-designations, and rebuttal/context-designations, each side shall be charged only with the time needed to read or play by videotape its own designations, counter-designations or context designations. When conferring to resolve any objections, the parties shall also confer to try to agree upon the allocation of time to be charged to each party with regard to deposition designations.

VIII. THE PARTIES' BRIEF STATEMENTS OF INTENDED PROOFS

76. Plaintiffs' Brief Statement of Intended Proofs is attached as Tab 10.

77. Defendants' Brief Statement of Intended Proofs is attached as Tab 11.

IX. MISCELLANEOUS ISSUES

78. Plaintiffs' list of Miscellaneous Issues is attached as Tab 12.

79. Defendants' list of Miscellaneous Issues is attached as Tab 13.

X. CERTIFICATION OF TWO-WAY COMMUNICATION

REDACTED

XI. ORDER TO CONTROL COURSE OF ACTION

82. This order shall control the subsequent course of the action unless modified by the Court to prevent manifest injustice.

XII. AMENDMENT OF PLEADINGS

83. None.

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SO ORDERED this _____ day of April, 2007.

_____
Chief Judge

Tab 1

JOINT STATEMENT OF ADMITTED FACTS REQUIRING NO PROOF

The Parties

1. Plaintiff Janssen Pharmaceutica N.V., a wholly-owned subsidiary of Johnson & Johnson, is a corporation organized and existing under the laws of Belgium and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

2. Plaintiff Janssen, L.P., a wholly-owned subsidiary of Johnson & Johnson, is a limited partnership organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

3. Plaintiff Janssen Pharmaceutica N.V. and Plaintiff Janssen L.P. (collectively, "Janssen") have certain rights to the patent-in-suit, U.S. Patent No. 4,663,318 ("the '318 Patent").

4. Plaintiff Synaptech, Inc. ("Synaptech") is a company organized and existing under the laws of the State of New York and has its principal place of business care of Schwartz & Salomon, P.C., 225 Broadway, New York, New York 10007.

5. Defendant Alphapharm Pty., Ltd. ("Alphapharm") is a corporation organized under the laws of Australia with a principal place of business at Chase Building 2, 1 Wentworth Park Road, Glebe NSW 2037 Australia. Alphapharm does not dispute jurisdiction in this case.

6. Defendant Barr Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at Two Quaker Road, P.O. Box 2900, Pomona, NY. Barr Laboratories, Inc. conducts business in the State of Delaware.

7. Defendant Barr Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677. Barr Pharmaceuticals, Inc. conducts business in the State of Delaware. Barr Laboratories, Inc. is a wholly-owned subsidiary of Defendant Barr Pharmaceuticals, Inc. (collectively, "Barr").

8. Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized under the laws of the State of New Jersey and has its principal place of business at 200 Somerset Corporate Blvd., 22 West, Building 2, 7th floor, Bridgewater, New Jersey 08807. Dr. Reddy's Laboratories, Inc. admitted jurisdiction exists in this case.

9. Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India with a principal place of business in India. Dr. Reddy's Laboratories, Ltd. admitted jurisdiction exists in this case. Defendant Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Defendant Dr. Reddy's Laboratories Ltd. (collectively, "Dr. Reddy's").

10. Defendant Mylan Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Defendant Mylan Pharmaceuticals, Inc. admitted that it is subject to personal jurisdiction in this case.

11. Defendant Mylan Laboratories, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania and having its principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317. Defendant Mylan Laboratories, Inc. did not dispute personal jurisdiction in this case. Defendant Mylan

Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Mylan Laboratories, Inc. (collectively, "Mylan").

12. Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at One Ram Ridge Road, Spring Valley, New York 10977. Defendant Par Pharmaceutical, Inc. conducts business in the State of Delaware.

13. Defendant Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware and conducts business in the State of Delaware. Defendant Par Pharmaceutical, Inc. is a wholly owned subsidiary of Defendant Par Pharmaceutical Companies, Inc.

14. Defendant Purepac Pharmaceutical Co. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 14 Commerce Drive, Suite 301, Cranford, New Jersey 07016. Defendant Purepac conducts business in the State of Delaware.

15. Defendant Alpharma, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at One Executive Drive, Fort Lee, New Jersey 07024. Defendant Alpharma conducts business in the State of Delaware. Defendant Purepac Pharmaceutical, Inc. is a wholly owned subsidiary of Defendant Alpharma, Inc. (collectively, "Purepac" or "Alpharma").

16. Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 1090

Horsham Road, North Wales, Pennsylvania 19454. Defendant Teva Pharmaceuticals USA, Inc. did not dispute jurisdiction in this case.

17. Defendant Teva Pharmaceutical Industries Ltd. is a foreign corporation organized and existing under the laws of Israel with its principal place of business in Israel. Defendant Teva Pharmaceutical Industries Ltd. did not dispute jurisdiction in this case. Defendant Teva Pharmaceutical USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. (collectively, "Teva").

Patent-in-Suit

18. The '318 Patent, titled "Method of Treating Alzheimer's Disease," issued on May 5, 1987.

19. The application which led to the '318 Patent was filed on January 15, 1986.

20. Bonnie Davis is the named inventor of the '318 Patent.

21. The term of the '318 Patent runs through December 14, 2008.

22. Synaptech, Inc. owns all right, title, and interest in the '318 Patent.

23. On November 30, 1995, Janssen entered into an exclusive license agreement with Synaptech with respect to the '318 Patent. Pursuant to that agreement, Janssen currently markets galantamine hydrobromide tablets in the U.S. under the trademark RAZADYNE and previously marketed galantamine hydrobromide tablets in the U.S. under the trademark REMINYL®.

24. As exclusive licensee, Janssen has the right to sue and recover damages for any infringement of the '318 Patent.

Plaintiffs' Approved Drug Product

25. Janssen is the holder of an approved new drug application, NDA No. 21-169, for galantamine hydrobromide tablets. That NDA was approved by FDA on February 28, 2001, and covers three strengths of tablet – Eq. 4 mg base, 8 mg base, and 12 mg base. The sole indication or condition of use for which galantamine hydrobromide tablets are approved in NDA No. 21-169 is the treatment of mild to moderate dementia of the Alzheimer's type.

26. Pursuant to FDA's approval, Janssen currently markets galantamine hydrobromide tablets for the treatment of mild to moderate dementia of the Alzheimer's type under the trademark RAZADYNE. Until 2005, Janssen marketed its galantamine hydrobromide tablets under the trademark REMINYL®.

27. At Janssen's request, FDA listed the '318 Patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 21-169.

28. The '318 Patent qualifies for listing in the Orange Book in connection with NDA No. 21-169 because it claims an approved use of the drug product that is the subject of that NDA.

Abbreviated New Drug Application, Paragraph IV Certification Filers

29. On or before May 11, 2005, Alphapharm submitted to the FDA an Abbreviated New Drug Application ("ANDA") (No. 77-603) and certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a so-called "Paragraph IV certification"), seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product before the expiration of the '318 Patent.

30. Plaintiffs sued Alphapharm for infringement of the '318 Patent on or about June 21, 2005.

31. On or before May 13, 2005, Barr submitted to the FDA an ANDA (No. 77-605) and Paragraph IV certification, seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product before the expiration of the '318 Patent.

32. Plaintiffs sued Barr for infringement of the '318 Patent on June 10, 2005.

33. On or before April 29, 2005, Dr. Reddy's submitted to the FDA an ANDA (No. 77-593) and Paragraph IV certification, seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product before the expiration of the '318 Patent.

34. Plaintiffs sued Dr. Reddy's for infringement of the '318 Patent on June 10, 2005.

35. On or before April 27, 2005, Mylan submitted to the FDA an ANDA (No. 77-590) and Paragraph IV certification, seeking approval to manufacture, market, and sell of generic version of Plaintiffs' RAZADYNE product before the expiration of the '318 Patent.

36. Plaintiffs sued Mylan for infringement of the '318 Patent on June 7, 2005.

37. On or before May 17, 2005, Par submitted to the FDA an ANDA (No. 77-604) and Paragraph IV certification, seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product before the expiration of the '318 Patent.

38. Plaintiffs sued Par for infringement of the '318 Patent on June 29, 2005.

39. On or before April 29, 2005, Purepac submitted to the FDA an ANDA (No. 77-585) and Paragraph IV certification, seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product prior to the expiration of the '318 Patent.

40. Plaintiffs sued Purepac and Alpharma for infringement of the '318 Patent on June 10, 2005.

41. In early 2006, the Actavis Group, a corporation organized under the laws of Iceland that conducts business in the State of Delaware, acquired the generic pharmaceutical business of Alpharma, including Alpharma's former subsidiary, Purepac.

42. After the acquisition by Actavis Group, Plaintiffs and Alpharma agreed to substitute Actavis Group for Alpharma for all purposes in this action.

43. On or before April 22, 2005, Teva submitted to the FDA an ANDA (No. 77-587) and Paragraph IV certification, seeking approval to manufacture, market, and sell a generic version of Plaintiffs' RAZADYNE product prior to the expiration of the '318 Patent.

44. Plaintiffs sued Teva for infringement of the '318 Patent on June 3, 2005.

45. Barr and Alphapharm are actively litigating this case.

46. All seven cases were consolidated on October 12, 2005.

Stipulation Not to Contest Infringement

47. By Stipulation Not to Contest Infringement, dated December 2, 2005, Defendants stipulated that each of the commercial use or sale of the drug products described in ANDAs No. 77-585 (Purepac), No. 77-587 (Teva), No. 77-590 (Mylan), No. 77-593 (Dr. Reddy's), No. 77-603 (Alphapharm), No. 77-604 (Par), and No. 77-605 (Barr) infringes claims 1 and 4 of the '318 Patent if valid and enforceable under 35 U.S.C. § 271(b).

48. Plaintiffs stipulated that they will not assert that the commercial manufacture, use, sale, offer for sale, or importation of the drug products described in abbreviated new drug applications No. 77-585 (Purepac), No. 77-587 (Teva), No. 77-590

(Mylan), No. 77-593 (Dr. Reddy's), No. 77-603 (Alphapharm), No. 77-604 (Par), and No. 77-605 (Barr) infringes any claim of the '318 Patent other than claims 1 and 4.

Status of the Defendants

49. Par Pharmaceutical, Inc. withdrew its Paragraph IV certification in favor of a Paragraph III certification. Thus, Par no longer alleges that the '318 Patent is invalid. Judge Jordan dismissed without prejudice the case against Par on May 5, 2006.

50. The proceedings against Purepac and Actavis Group have been stayed as of May 5, 2006. Purepac and Actavis Group have agreed to be bound by the decision of the trial court in this case.

51. The proceedings against Dr. Reddy have been stayed as of May 31, 2006. Dr. Reddy agreed to be bound by the decision of the trial court in this case.

52. The proceedings against Mylan have been stayed as of June 19, 2006. Mylan agreed to be bound by the decision of the trial court in this case.

53. The proceedings against Teva have been stayed as of July 20, 2006. Teva agreed to be bound by the decision of the trial court in this case.

Miscellaneous

54. Five drug products have been approved by the FDA for the treatment of Alzheimer's disease: Cognex® (tacrine), Aricept® (donepezil), Exelon® (rivastigmine), RAZADYNE (galantamine), and Namenda® (memantine).

Tab 2

PLAINTIFFS' STATEMENT OF ISSUES OF FACT WHICH REMAIN TO BE LITIGATED

Plaintiffs respectfully submit the following list of issues of fact that remain to be litigated. If any statement included herein as an issue of fact properly should be considered an issue of law, then we respectfully request that it be so considered. To the extent that Plaintiffs' statement of issues of law contain issues of fact, those issues are incorporated herein by reference. Plaintiffs reserve the right to revise this list based on the outcome of pending motions and evidence presented at trial.

In addition to the issues of fact which remain to be litigated identified below, Plaintiffs hereby refer to and incorporate by reference the evidence of patent validity set forth in Plaintiffs' expert reports and Rule 30(b)(6) deposition testimony.

Defendants have stipulated to infringement of claims 1 and 4 of the '318 Patent. Defendants have alleged, in their interrogatory responses, that the '318 Patent is invalid on the grounds of anticipation, obviousness, and enablement/written description.

I. VALIDITY

A. Whether Defendants can prove by clear and convincing evidence that claims 1 and 4 of '318 Patent are invalid.

B. Anticipation:

1. Whether Defendants have shown by clear and convincing evidence that the single prior art reference that they assert is anticipating – P.A. Bhasker, *Medical Management of Dementia*, The Antiseptic, 71(1):45-47 (1974) (hereinafter "*Bhasker*") – is a printed publication disclosing all of the elements of claims 1 and 4 of the '318 Patent and enabling a person of ordinary skill in the art to make and use the claimed invention. Plaintiffs will present evidence, for example, that, far

from disclosing galantamine as a treatment for Alzheimer's disease, *Bhasker* nowhere describes Alzheimer's disease, expressly describes the category of "progressive dementia" – which Defendants contend includes Alzheimer's Disease – as not treatable, and only mentions "Gallanthamine" in the entirely different context of "local brain damage."

C. Non-obviousness: Whether Defendants can prove by clear and convincing evidence that the invention described in claims 1 and 4 of the '318 Patent was obvious to a person of ordinary skill in the art at the time the claimed invention was made in light of the scope and content of the prior art, the differences between claims 1 and 4 of the '318 Patent and the prior art, the level of ordinary skill in the art at that time, and the objective evidence of non-obviousness.

1. Person of Ordinary Skill in the Art: The level of ordinary skill in the art as of the priority date of claims 1 and 4 of the '318 Patent, which Plaintiffs contend is a medical physician with clinical experience treating elderly patients with Alzheimer's disease (which is presenile dementia and senile dementia of the Alzheimer's type).

2. Objective Factors of Non-obviousness: The nature and extent of any objective consideration that relates to the obviousness or nonobviousness of the subject matter of claims 1 and 4 of the '318 Patent. Plaintiffs will present evidence that:

   i. There was a long felt need for a treatment for Alzheimer's disease that was met, at least in part, by the invention claimed in the '318 Patent. At the time of filing of the application that became the '318 Patent, it was widely recognized that Alzheimer's disease was a wide-spread and

growing epidemic among the elderly, that imposed grave and inescapable suffering upon the patient and his or her caregivers and tremendous economic and institutional costs on society. There was at the time no treatment for the disease, including no treatment for the relentless cognitive decline that is the signature symptom of the disease.

ii. Before and after the filing of the application that became the '318 Patent, there were many failed attempts to develop a treatment for Alzheimer's disease. Those failures include trials with blood thinners and anticoagulants, based on the erroneous belief that the symptoms of Alzheimer's disease were related to poor blood flow in the brain; metabolic enhancers and so-called "nootropics," based on the erroneous belief that those symptoms were related to poor brain metabolism; and chelating agents, from a mistaken belief that the disease was related to aluminum in the brain. There were many false leads even among the cholinesterase inhibitors – the class of drugs that includes the galantamine of the invention. In 1996, ten years after the filing of the patent application, at least 16 cholinesterase inhibitors had been taken into clinical trials, yet only four were ultimately approved (including the galantamine of the invention), and of those four, one is no longer prescribed, due to serious safety issues. The vast majority of cholinesterase inhibitors that were tried as possible treatments for Alzheimer's disease failed, as did the other cholinergic approaches that were tried, including acetylcholine precursors and muscarinic agonists.

iii. Before and after the '318 Patent, those skilled in the art were skeptical that galantamine would work as a treatment for Alzheimer's disease. This skepticism was expressed, for example, both in the technical literature at the time and in the actions of the many pharmaceutical companies that rejected the efforts of Dr. Bonnie Davis, the named inventor of the '318 Patent, to interest them in developing a galantamine drug product for treatment Alzheimer's disease on the basis that they did not believe that galantamine would prove successful.

iv. The invention claimed in the '318 Patent has achieved recognition in the industry including licensing, copying, and acquiescence – as evidenced, for example, by the fact that now eleven companies want to market a galantamine drug product for treatment of Alzheimer's disease and have filed "Paragraph III" certifications agreeing to refrain from doing so until expiration of the '318 Patent.

v. The invention claimed in the '318 Patent has yielded unexpected results. For example, in addition to providing a therapeutically effective method of alleviating the cognitive decline associated with the disease, galantamine has been found as well to provide therapy for the non-cognitive symptoms of the disease, to ease the burden on caregivers, and possibly to slow progression of the disease itself. One possible explanation for the benefits associated with galantamine in treating Alzheimer's disease is that galantamine has been shown to have two mechanisms of action, acting both as an inhibitor of the cholinesterase enzyme to enhance acetylcholine

levels in the brain and as an "allosteric modulator" that enhances the response of the nicotinic receptor to acetylcholine. This second mechanism of action was neither known nor expected at the time of filing of the application for patent and distinguishes galantamine from all the other approved cholinesterase inhibitors.

vi. RAZADYNE, the commercial embodiment of the '318 Patent is a commercial success and that success is the result of the use of galantamine to treat Alzheimer's disease as claimed in the patent.

3. Defendants have not indicated the relevance of any other objective indicia in their interrogatory responses. Should Defendants attempt to introduce previously-undisclosed evidence related to the objective indicia of nonobviousness, however, Plaintiffs respectfully reserve the right to supplement this section of the Joint Pretrial Order and otherwise respond.

D. Enablement: Whether Defendants have shown by clear and convincing evidence that each of the asserted claims of the '318 Patent is invalid for failure to comply with the enablement requirement in 35 U.S.C. § 112.

E. Written description: Whether Defendants have shown by clear and convincing evidence that each of the asserted claims of the '318 Patent in valid for failure to comply with the written description requirement in 35 U.S.C. § 112.

II. RELIEF AGAINST DEFENDANTS

A. Whether Plaintiffs are entitled to a permanent injunction against Defendants and those persons in active concert or participation with any of them, from making, using selling, or offering to sell in the United States, or importing into the United States, the galantamine

hydrobromide tablets for which approval is sought in Defendants' ANDAs, or any galantamine hydrobromide product that infringes or induces or contributes to the infringement of the '318 Patent, until expiration of that patent.

B. Whether Plaintiffs are entitled to an order under 35 U.S.C.§ 271(e)(4) ordering that Defendants' ANDAs for galantamine hydrobromide tablets not be approved until the expiration of the '318 Patent and any associated exclusivity period.

C. Whether this is an exceptional case, finding appropriate an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285.

D. The appropriate award of Plaintiffs' costs and expenses in this action.

III. FACTS AS TO WHICH PLAINTIFFS CONTEND THAT NO REASONABLE BASIS FOR DISPUTE EXISTS, BUT AS TO WHICH DEFENDANTS NEVERTHELESS REFUSE TO AGREE

Anticipation

A Defendant Barr is not aware of any reference published before January 15, 1986 that cites P.A. Bhasker, *Medical Management of Dementia*, The Antiseptic, 71(1):45-47 (1974).

B. Defendant Alphapharm is not aware of any reference published before January 15, 1986 that cites P.A. Bhasker, *Medical Management of Dementia*, The Antiseptic, 71(1):45-47 (1974).

Patent History

A. In response to the application that led to the '318 Patent, the U.S. Patent and Trademark Office ("PTO") issued an Office Action dated April 10, 1986 to the inventor, Dr. Bonnie Davis.

B. Dr. Davis responded to that Office Action on September 9, 1986. That Response is marked as having been received on September 17, 1986 by the group within the PTO examining Dr. Davis' patent application.

C. On October 20, 1986, the PTO issued a Notice of Allowance to Dr. Davis, allowing all pending claims without any further inquiries or requirements.

Abbreviated New Drug Application, Paragraph III Certification Filers

A. Ten additional companies filed ANDAs seeking to market generic copies of RAZADYNE. These companies did not challenge the validity or enforceability of the '318 paragraph. Instead, each company provided FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) (a so-called "Paragraph III Certification"), which states that the applicant for generic approval will not seek to market the product that is the subject of the ANDA before the expiration of patents listed in the Orange Book.

B. While Defendants do not appear to dispute the existence of the ten Paragraph III filers, they nevertheless refused to permit Plaintiffs to include any reference to the Paragraph III filers in the list of Joint Statement Admitted Facts Not Requiring Proof, Tab 1 above, on "relevance" grounds.

C. In any event, the ten Paragraph III filers are summarized below:

ANDA Filer	ANDA Filing and Paragraph III Certification Date	ANDA Number
Apotex, Inc.	on or before August 25, 2005	ANDA No. 77-781
Cobalt Pharmaceuticals, Inc.	on or before October 14, 2005	ANDA No. 77-823

ANDA Filer	ANDA Filing and Paragraph III Certification Date	ANDA Number
Eon Labs Manufacturing, Inc.	on or before May 12, 2005	ANDA No. 77-607
IVAX Pharmaceuticals, Inc.	on or before April 29, 2005	ANDA No. 77-609
Mutual Pharmaceuticals Co.	on or before April 22, 2005	ANDA No. 77-586
Ranbaxy Laboratories, Ltd.	on or before May 6, 2005	ANDA No. 77-588
Roxanne Laboratories, Inc.	on or before April 26, 2005	ANDA No. 77-608
Sandoz, Inc.	on or before May 11, 2005	ANDA No. 77-589
Sun Pharmaceutical Industries, Ltd.	on or before May 16, 2005	ANDA No. 77-592
Watson Laboratories, Inc.	on or before August 26, 2005	ANDA No. 77-767

D. As noted above, Par Pharmaceuticals, Inc. was originally a defendant in this lawsuit, but converted its Paragraph IV certification to a Paragraph III certification and thus no longer challenges the validity or enforceability of the '318 Patent and will instead wait until patent expiration before attempting to sell and market its generic version of RAZADYNE. As a result, there are currently a total of eleven Paragraph III filers.

Tab 3

DEFENDANTS' STATEMENT OF ISSUES OF FACT THAT REMAIN TO BE LITIGATED

To the extent that Defendants' statement of issues of law contains issues of fact, those issues are incorporated herein by reference. Should the Court determine that any issue identified in this list as an issue of fact is more properly considered an issue of law, Defendants incorporate such issues by reference into its statement of issues of law.

I. Anticipation

1. The qualifications and knowledge of a person of ordinary skill in the art as of January 15, 1986.

2. Whether, as of January 15, 1986, P.A. Bhasker's article, *Medical Management of Dementia* ("the Bhasker article"), published in the "Antiseptic" in 1974, disclosed to a person of ordinary skill in the art methods of treating dementias.

3. Whether, as of January 15, 1986, a person of ordinary skill in the art understood the Bhasker article's disclosure of irreversible "dementias" characterized by "a progressive fall-out of neurons and the course of the illness is rapidly downhill" as encompassing Alzheimer's disease and related dementias.

4. Whether, as of January 15, 1986, the Bhasker article disclosed to a person of ordinary skill in the art that irreversible progressive dementias can be treated by administering small daily doses of galanthamine to facilitate acetylcholine activity and thereby restore higher cortical functions, such as memory, thinking, speech and movement.

5. Whether, as of January 15, 1986, a person of ordinary skill in the art recognized that diminution in higher cortical functions, such as memory and thinking, are symptoms of Alzheimer's disease.

6. Whether, as of January 15, 1986, the Bhasker article disclosed to a person of ordinary skill in the art that small daily doses of galanthamine are therapeutically effective to improve higher cortical functions.

7. Whether, as of January 15, 1986, the Bhasker article anticipated the claimed invention of the '318 patent.

II. Obviousness

8. The qualifications and knowledge of a person of ordinary skill in the art as of January 15, 1986.

9. The scope and content of the prior art as of January 15, 1986.

10. The differences, if any, between the inventions claimed in claims 1 and 4 of the '318 patent and the prior art as of January 15, 1986.

11. Whether, as of January 15, 1986, it was known to a person of ordinary skill in the art that the neurotransmitter acetylcholine was found to be diminished in the brains of patients with Alzheimer's disease and related dementias.

12. Whether, as of January 15, 1986, it was known to a person of ordinary skill in the art that inhibiting the breakdown of acetylcholine with a reversible cholinesterase inhibitor that crosses the blood brain barrier has the capability to improve cognitive function, such as memory, in patients with Alzheimer's disease and related dementias.

13. Whether, as of January 15, 1986, a person of ordinary skill in the art would have considered the prior art studies with the reversible cholinesterase inhibitors physostigmine and tacrine as proof of concept in humans that a reversible cholinesterase inhibitor that penetrates the blood-brain barrier has the capability to improve cognitive function, such as memory, in patients with Alzheimer's disease and related dementias.

14. Whether, as of January 15, 1986, a person of ordinary skill in the art would have been motivated by the prior art to find a reversible cholinesterase inhibitor that was longer-acting and had a more favorable side-effect profile than physostigmine and/or tacrine as a method of treating Alzheimer's disease and related dementias.

15. Whether, as of January 15, 1986, it was known to a person of ordinary skill in the art that galanthamine was a reversible cholinesterase inhibitor that penetrated the blood-brain barrier and had the capability to restore higher cortical functions, such as memory, in humans.

16. Whether, as of January 15, 1986, it was known to a person of ordinary skill in the art that galanthamine had been reported in the prior art as being safe and tolerable in humans.

17. Whether, as of January 15, 1986, it was known to a person of ordinary skill in the art that galanthamine had been reported in the prior art as being a longer-acting cholinesterase inhibitor than physostigmine.

18. Whether, as of January 15, 1986, it was known to a person of ordinary skill in the art that galanthamine had been reported in the prior art as having a more favorable side-effect profile than tacrine.

19. Whether, as of January 15, 1986, a person of ordinary skill in the art, would have had a reasonable expectation that galanthamine could treat Alzheimer's disease and related dementias when administered in therapeutically effective amounts.

20. Whether, as of January 1986, the prior art disclosed to a person of ordinary skill in the art dosages of galanthamine that fall within the lower end of the range of 10 to 2000 mg that when administered orally were shown to be therapeutically effective.

III. Secondary Considerations of Non-obviousness

21. Whether Plaintiffs have provided sufficient evidence of secondary considerations of non-obviousness so as to overcome a showing that the '318 patent is obvious.

22. Whether Plaintiffs have established that there is a legally and factually sufficient nexus between the claimed inventions in Claims 1 and 4 and Plaintiffs' evidence of non-obviousness.

23. Whether any evidence of non-obviousness established by Plaintiffs is of sufficient weight to override a prima facie case of obviousness.

IV. Enablement

24. Whether Dr. Davis provided any experimental data in the '318 patent to demonstrate, as of January 1986, that administering galanthamine in therapeutically effective amounts treats Alzheimer's disease and related dementias in patients, and if not, whether a person of ordinary skill in the art would have accepted without question that administering galanthamine in therapeutically effective amounts treats Alzheimer's disease and related dementias.

25. Whether Dr. Davis provided any experimental data in the '318 patent to demonstrate that, as of January 1986, all amounts in the range from 10 to 2000 mg in claim 4 were therapeutically effective to treat Alzheimer's disease and related dementias, and if not, whether a person of ordinary skill in the art would have accepted without question that all amounts in the range of 10 to 2000 mg were therapeutically effective to treat Alzheimer's disease and related dementias in patients.

26. Whether all amounts in the range from 10 to 2000 mg in claim 4 are therapeutically effective to treat Alzheimer's disease and related dementias.

V. Requested Relief

27. Whether a judgment should be entered providing for FDA approval for Barr and Alphapharm's ANDAs to commercially make, use, or sell galanthamine hydrobromide tablets or any drug product containing galanthamine hydrobromide for the treatment of mild to moderate Alzheimer's Disease before the expiration of the '318 patent.

Tab 4

PLAINTIFFS' STATEMENT OF ISSUES OF LAW WHICH REMAIN TO BE LITIGATED

Clear and Convincing Evidence/Presumption of Validity

1. Whether Barr and Alphapharm have overcome the presumption of validity and proven by clear and convincing evidence that Claim 1 and Claim 4 of the '318 Patent are invalid. 35 U.S.C. § 282; *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986). The presumption remains intact and Barr and Alphapharm retain their burden of proof throughout the litigation. *Id.*

Anticipation

1. Whether Barr and Alphapharm have proven by clear and convincing evidence that Claim 1 of the '318 Patent is invalid under 35 U.S.C. § 102 as anticipated by P.A. Bhasker, *Medical Management of Dementia*, The Antiseptic, 71(1):45-47 (1974) ("*Bhasker*"). 35 U.S.C. §§ 102, 282; *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004).

a. Disclosure of claim elements. Barr and Alphapharm must prove by clear and convincing evidence that *Bhasker* necessarily discloses, either expressly or inherently, each and every element of Claim 1 of the '318 Patent. *Metabolite Labs., Inc.*, 370 F.3d at 1367.

b. Printed publication. Barr and Alphapharm must show by clear and convincing evidence that *Bhasker* is a "printed publication" for purposes of 35 U.S.C. §§ 102 and 103. 35 U.S.C. §§ 102, 103; *In re Cronyn*, 890 F.2d 1158 (Fed. Cir. 1989). Public accessibility is the touchstone of the question whether a reference satisfies the requirements of a "printed publication." *Id.* at 1160.

c. Enablement. Finally, Barr and Alphapharm must show by clear and convincing evidence that *Bhasker* would enable a person of ordinary skill in the art to make and use the invention claimed in the '318 Patent. *Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

Obviousness

1. Whether Barr and Alphapharm have proven by clear and convincing evidence that Claims 1 and 4 of the '318 Patent are invalid under 35 U.S.C. § 103 such that the invention of these claims would have been obvious at the time of the invention to a person of ordinary skill in the art. 35 U.S.C. § 103; *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

a. Relevant considerations. Obviousness is a legal determination based on several issues of fact: (1) the scope and content of the prior art; (2) the level of skill of a person of ordinary skill in the art; (3) the differences between the claimed invention and the teachings of the prior art; and (4) objective indicia of obviousness, *e.g.*, failure of others, long-felt but unmet need, commercial success, and unexpected results. *Id.* at 17-18.

b. Motivation to combine. Barr and Alphapharm must prove by clear and convincing evidence that there is a suggestion, motivation, or teaching in the prior art references that would have led a person of ordinary skill to select the references for combination. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1361 (Fed. Cir. 1998).

c. Reasonable Expectation of Success. Barr and Alphapharm must prove by clear and convincing evidence that a person of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of the prior art references. *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003).

Enablement

1. Whether Barr and Alphapharm have proven by clear and convincing evidence that the written description of the '318 Patent would not enable a person of ordinary skill in the art to make and use the claimed invention. 35 U.S.C. § 282; 35 U.S.C. § 112; *Bruning v. Hirose*, 161 F.3d 681, 686 (Fed. Cir. 1998).

a. Additional experimentation. A patent may be enabled even if some experimentation is required, provided it is not unduly excessive. *Id.* "Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development." *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

Written Description

1. Whether Barr and Alphapharm have proven by clear and convincing evidence that Claim 4 of the '318 Patent is invalid for failure to comply with the written description requirement of 35 U.S.C. § 112. 35 U.S.C. § 282; 35 U.S.C. § 112; *In re Hayes Microcomputer Prods., Inc. Patent Litig.*, 982 F.2d 1527, 1534 (Fed. Cir. 1992); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63 (Fed. Cir. 1991).

Claim Construction

1. To the extent defendants' invalidity attacks require construction of the claims, such claim construction is a matter of law to be decided by the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). Claims are to be given their "ordinary and customary meaning" – that is, "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005).

Exceptional Case

1. Whether this case is "exceptional" such that an award of attorney fees to Plaintiffs is appropriate pursuant to 35 U.S.C. § 285. A finding of willful infringement is not necessary to support an exceptional case determination. *Yamanouchi Pharm. Co. Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000); *Forest Labs. Inc. v. Ivax Pharms., Inc.*, Civ. Action No. 03-891-JJF, 2007 WL 788897, at *3 (D. Del. Mar. 15, 2007). Rather, such a finding is based on the totality of circumstances. *Yamanouchi*, 231 F.3d at 1347.

Tab 5

DEFENDANTS' STATEMENT OF ISSUES OF LAW
THAT REMAIN TO BE LITIGATED

Defendants submit this Statement of Issues of Law that remain to be litigated without waiving prior positions taken by Defendants. Defendants reserve the right to litigate legal issues raised by Plaintiffs even if not specifically set forth herein. To the extent that any issues of fact set forth in Defendants' Statement of Facts that remain to be litigated may be considered as issues of law, Defendants hereby incorporate those issues by reference. Defendants also incorporate by reference any portion of Defendants' Brief Statement of Intended Proofs that raises additional legal issues.

I. INVALIDITY

A. Whether the Asserted Claims of U.S. Patent No. 4,663,318 Are Invalid as Anticipated Under 35 U.S.C. § 102(b) by P.A. Bhasker's "Medical Management of Dementia"

35 U.S.C. § 102(b) provides, *inter alia*, that a patent may not be obtained if the invention was anticipated by "a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Whether a claimed invention is anticipated by a prior printed publication is a question of fact. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991).

A single prior art reference is invalidating if the elements and limitations of the asserted claim(s) are found within that reference, "either expressly or inherently." *Scripps Clinic*, 927 F.2d at 1576; *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1369 (Fed. Cir. 2005). "[T]he question of whether a claim limitation is inherent in a prior art reference is a factual question on which evidence may be introduced." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (citing *Continental Can Co. USA v.*

Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991)). That evidence is viewed through the lens of persons of ordinary skill in the art. *Continental Can Co.*, 948 F.2d at 1268 (Fed. Cir. 1991). "'[I]nherency operates to anticipate entire inventions as well as single limitations within an invention.'" *Matsushita Elec. Indus. Co. Ltd. v. Cinram Int'l, Inc.*, 299 F. Supp. 2d 348, 362 (D. Del. 2004) (citing *Schering Corp. v. Geneva Pharms. Inc.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). "Recognition of the inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation." *Id.*

Like the issue of inherency in particular, the issue of anticipation in general is determined from the perspective of a person of ordinary skill in the field of the invention. *Scripps Clinic*, 927 F.2d at 1576 (Fed. Cir. 1991). Therefore, where a reference does not expressly disclose a claim element(s), there is still anticipation where a person of ordinary skill in the art would understand the reference as disclosing that element(s), and such element(s) was within the knowledge of that person. *Heliflex Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1139, 1347 (Fed. Cir. 2000). A reference anticipates "even if it does not specifically disclose" the claim limitation if the limitation "is within the knowledge of a skilled artisan." *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995). Indeed, this Court has held:

> . . . [A]nticipation may be established if a missing claim element is within the knowledge of one of ordinary skill in the art. (Citation omitted). This 'gap in the reference may be filled with recourse to extrinsic evidence.' (Citation omitted). 'Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be recognized by persons of ordinary skill.' (Citation omitted). Thus, extrinsic evidence of the knowledge of one of ordinary skill in the art is relevant in situations where the common knowledge of technologists is not recorded in the reference; that is, where

> technological facts are known to those in the field of the invention, albeit not known to judges. (Citation omitted).

Discovision Assocs. v. Disc Mfg., Inc., 25 F. Supp. 2d 301, 344 (D. Del. 1998). Moreover, "inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created" but rather when the patent application is filed. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed Cir. 2005).

Next, an anticipating reference "need not recite the elements of the patent claim in language identical to the language used in the claim, so long as the reference teaches the entirety of the invention." *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 438 F. Supp. 2d 479, 485 (D. Del. 2006). The Federal Circuit has explained that "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006). "Recognition of the inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation." *Matsushita Elec.*, 299 F. Supp. 2d at 362 (citing *Schering Corp. v. Geneva Pharms. Inc.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003)). In addition, "[a] reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. Thus, the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis." *Celeritas Techs. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) (citation omitted).

B. Whether the Asserted Claims of U.S. Patent No. 4,663,318 are Invalid for Obviousness Under 35 U.S.C. § 103

35 U.S.C. § 103 provides, *inter alia*, that a patent may not be obtained if the differences between the subject matter sought to be patented and the prior art would

have been obvious to a person having ordinary skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The question of whether a claimed invention is unpatentable as obvious under 35 U.S.C. § 103 is a question of law based on underlying findings of fact. *McNeil-PPC, Inc. v. Perrigo Co.*, 337 F.3d 1362, 1368 (Fed. Cir. 2003). The underlying factual inquiries are: 1) the level of ordinary skill in the pertinent art at the time of the invention; (2) the scope and content of the prior art; (3) the differences, if any, between the claimed invention and the prior art; and (4) secondary considerations, if any, of non-obviousness. *Graham*, 383 U.S. at 17-18; *McNeil-PPC*, 337 F.3d at 1368. Although the United States Supreme Court[1] is considering a case in which the obviousness standard is at issue, currently a party has to demonstrate a motivation or suggestion to combine or modify prior art references to produce the claimed invention, coupled with a reasonable expectation of success. *Brown and Williamson Tobacco Corp. v. Phillip Morris Inc.*, 229 F.3d 1120, 1124-25 (Fed. Cir. 2000).

1. **Level of Ordinary Skill in the Art**

35 U.S.C. § 103 requires that a claim be declared invalid when the invention set forth in the claim can be said to have been obvious to one of ordinary skill in the art to which the patent pertains. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, a court should consider the following factors relevant to the inquiry: 1) educational level of the inventor; 2) type of problems encountered in the art; 3) prior art solutions; 4) rapidity of innovation; 5)

[1] The United States Supreme Court currently (oral argument is complete) is deciding *KSR Int'l. Co. v. Teleflex, Inc.*, Docket No. 04-1350, where the issue is whether the Federal Circuit erred in holding that a claimed invention cannot be held obvious in the absence of some "teaching, suggestion, or motivation" that would have led one of ordinary skill in that art to combine the relevant prior art in the manner claimed. That decision likely will have a significant impact on the law of obviousness and, thus, an impact on the Court's decision here.

sophistication of technology; and 6) educational level of active workers in the field. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 697 (Fed. Cir. 1983). "[N]ot all of the factors listed above may be present in every case, and one or more of these or other factors may predominate in a particular case." *Id.* at 696-97. This hypothetical person of ordinary skill in the art is presumed to know all of the teachings of the prior art references in the field of the invention at the time the invention was made. *Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1576 (Fed. Cir. 1984).

"The fact of near-simultaneous invention, though not determinative of statutory obviousness, is strong evidence of what constitutes the level of ordinary skill in the art." *Ecolochem, Inc. v. S. Cal. Edison, Co.*, 227 F.3d 1361, 1379 (Fed. Cir. 2000) (citation omitted). In fact, "[t]he issue of simultaneous invention is *directly tied* to the level of knowledge attributable to one of ordinary skill in the art." *Id.* (emphasis added); *see also Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 883 (Fed. Cir. 1998) (citing *In re Merck & Co.*, 800 F.2d 1091, 1098 (Fed. Cir. 1986) and *Medtronic, Inc. v. Daig Corp.*, 789 F.2d 903, 906 (Fed. Cir. 1986)) (recognizing "the relevance of contemporaneous independent invention to the level of ordinary knowledge or skill in the art").

2. The Scope and Content of the Prior Art

In determining whether the claimed invention falls within the scope of the relevant prior art, a court first examines "the field of the inventor's endeavor" and "the particular problem with which the inventor was involved" at the time the invention was made. *Monarch Knitting*, 139 F.3d at 881 (Fed. Cir. 1998). Prior art references which are not within the field of the inventor's endeavor may still properly be considered to fall

within the scope of the relevant prior art if "the field of the reference is reasonably pertinent to the problem the inventor is trying to solve." *Shatterproof Glass Corp. v. Libbey-Owens Ford. Co.*, 758 F.2d 613, 620 (Fed. Cir. 1985); *see also In re GPAC*, 57 F.3d at 1577-78 (Fed. Cir. 1995). In addition, the "particular problem with which the inventor was concerned" is not limited to the solution found by the inventor. *Monarch Knitting*, 139 F.3d at 881 (noting that "[d]efining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.").

3. **The Differences Between the Claimed Invention and the Prior Art**

In ascertaining the differences between the claims at issue and the prior art, a court must consider both the claimed invention and the prior art as a whole in light of the court's construction of the claims at issue. *See Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1479-80 (Fed. Cir. 1998). "The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that [the claimed invention] should be carried out and would have a *reasonable likelihood of success*, viewed in the light of the prior art'." *In re Dow Chem.*, 837 F.2d 469, 473 (Fed. Cir. 1988) (emphasis added).

A conclusion of obviousness may be made based on a single reference or a combination of prior art references if the references, taken as a whole, would have suggested the claimed invention to one of ordinary skill in the art. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Where a combination of prior art references is used to demonstrate obviousness, there must be "a reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the references . . .". *Smiths Indus. Med. Sys. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356 (Fed. Cir. 1999).

Such suggestion "may come from the references themselves, from knowledge by those skilled in the art that certain references are of special interest in the field, or even from the nature of the problem to be solved." *Id.* at 1347. It "need not be express and 'may come from the prior art, as filtered through the knowledge of one skilled in the art'." *Brown and Williamson*, 229 F.3d at 1125 (citation omitted). The ultimate determination of obviousness "does not require absolute predictability of success...[A]ll that is required is a reasonable expectation of success." *Id.* (citations omitted).

4. Objective Secondary Considerations of Nonobviousness

When a court reaches the conclusion that an asserted claim(s) is prima facie obvious, the patentee may attempt to present objective secondary considerations of nonobviousness. *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999). "The rationale for giving weight to the so-called 'secondary considerations' is that they provide objective evidence of how the patented device is viewed in the marketplace, by those directly interested in the product." *Demaco Corp. v. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391 (Fed. Cir. 1988) (citing *Graham,* 383 U.S. at 35-36). In the context of secondary considerations, "'argument' and 'conjecture' are insufficient." *Demaco Corp.*, 851 F.2d at 1391 (Fed. Cir. 1988) (citing *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546 (Fed. Cir. 1984)). "These legal inferences or subtests . . . focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation." *Graham*, 383 U.S. at 35-36.

In attempting to rely on objective evidence of nonobviousness, a patentee must establish a nexus between the evidence presented and the merits of the claimed

invention, *i.e.*, the patentee bears the burden of demonstrating "a legally and factually sufficient connection" between the evidence and the patented invention to demonstrate that the evidence offered does, in fact, corroborate the invention's nonobviousness. *In re Paulson*, 30 F.3d 1475, 1482 (Fed. Cir. 1994); *see also In re GPAC*, 57 F.3d at 1580 (Fed. Cir. 1995). Even when present, however, secondary considerations do not control the obviousness determination. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985). In situations where the required nexus is established, the evidence of secondary considerations must still be of sufficient weight to override a determination of obviousness based on primary considerations. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991). Such evidence will not save a patent where there is "strong evidence of obviousness." *Brown & Williamson*, 229 F.3d at 1131 (Fed. Cir. 2000).

a. *Commercial Success*

A patentee offering evidence of "commercial success" to support a nonobviousness determination bears the burden of showing that there was, in fact, commercial success, and showing the requisite nexus that any such success is attributable to the claimed invention rather than to other, unrelated factors such as advertising or unclaimed features of the product. *In re Paulson*, 30 F.3d at 1482. The weight that commercial success is given in an obviousness determination depends on both the extent of the commercial success, and the strength of the nexus between the commercial success and the merits of the claimed invention. *See Ashland Oil, Inc.*, 776 F.2d at 306 ("The objective evidence of secondary considerations may in any given case be entitled to more

or less weight, depending on its nature and its relationship to the merits of the invention.").

A purported showing of commercial success is "tenuous" where a product has "only broken even in the amount of money made, with the product's long-term profitability yet to be established." *Medpointe Healthcare, Inc. v. Hi-Tech Pharmacal Co., Inc.*, 115 Fed. Appx. 76, 80-81 (Fed. Cir. 2004). Even a strong showing of commercial success, without more, however, may be insufficient by itself to counter strong evidence of obviousness. *See Newell Cos., v. Kenney Mfg. Co.*, 864 F.2d 757, 769 (Fed. Cir. 1988); *Richardson-Vicks, Inc. v. Upjohn Co.*, 122 F.3d 1476, 1484 (Fed. Cir. 1997).

b. *Unexpected Benefits*

When a patentee attempts to rely on unexpected benefits as evidence of nonobviousness, a patentee must present evidence that the benefits claimed to be unexpected *actually* occur. *See In re J.A.M.C. De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984). Indeed, speculation or unproven hypotheses about what might become an "unexpected benefit" simply is not enough: "[I]t is well settled that unexpected results ***must be established by factual evidence***. 'Mere argument or conclusory statements . . . does not suffice.'" *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997) (citation omitted) (emphasis added). Thus, an applicant cannot prove unexpected benefits with "bare statements without objective evidentiary support." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). Moreover, the benefits must be proven to be unexpected compared with the closest prior art. *In re Baxter Travenol Labs*, 952 F.2d 388, 392 (Fed. Cir. 1991). Hence, when an invention "is said to achieve unexpected (*i.e.*

superior) results, those results must logically be shown as superior *compared* to the results achieved with other [prior art inventions]." *In re J.A.M.C.*, 736 F.2d at 705. When unexpected benefits are found to exist, a sufficient nexus must exist between the unexpected benefits and the claims of the invention that are at issue. *In re Gartside*, 203 F.3d 1305, 1321 (Fed. Cir. 2000).

c. ***Long-Felt But Unsolved Need***

A patentee may attempt to rely on evidence of a "long-felt but unsolved need" in the industry for the solution offered by a patented invention in attempting to overcome a *prima facie* finding that the invention is obvious. *Monarch Knitting*, 139 F.3d at 884. However, in the context of drugs for use in human therapy, a "long-felt" need is not present where there are already several other drugs of the same class in the marketplace. *See Aventis Pharma Deutschland GMBH v. Lupin, Ltd.*, 2006 WL 2008962, No. 2:05CV421, slip op. at *45 (E.D. Va. July 17, 2006) (finding that there "simply was no 'long-felt need'" for a drug where there were already "several effective" drugs of the same class already on the market).

d. ***Skepticism & Later Praise***

In order for a patentee to rely on skepticism and later praise as objective evidence of nonobviousness, the skepticism must be directed to whether the claimed invention would work in general, not to whether the invention was better suited to solve the problem addressed than other inventions already in existence. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1274-75 (Fed. Cir. 2004). Evidence of skepticism, even of experts, however, is entitled to little weight where the skepticism is addressed to concerns other

than the technical merit of the claimed invention. *Joy Tech., Inc. v. Manbeck*, 751 F. Supp. 225, 232 (D.D.C. 1990), *aff'd*, 959 F.2d 226 (Fed. Cir. 1992).

e. *Copying*

In the general area of patent law, a patentee may look to copying by others in the industry as objective evidence of nonobviousness. *Ecolochem*, 227 F.3d at 1380. However, in the specific area of patent law relating to generic drug companies and the ANDA process, copying "is what generic drug companies do. That is why their products are cheaper." *Aventis Pharma Deutschland GMBH,* 2006 WL 2008962, at *45 (E.D. Va. July 16, 2006) (citing Walker on Patents). In the ANDA context, "given that there is a statute in place that encourages generic drug companies to challenge patents . . . [a] copying argument is weak." *Id.* at *45.

f. *Licensing*

If a patentee attempts to rely on licensing to show the nonobviousness of the inventions, such licensing agreements "must be carefully appraised as to [their] evidentiary value." *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 908 (Fed. Cir. 1985). This is because there are many legitimate reasons to take a license which are *completely unrelated* to the nonobviousness of the patented subject matter, *i.e.*, a license may simply be mutually beneficial to the parties involved, it may be cheaper to take a license than to defend infringement suits, or any number of other business reasons. *Id.* at 907-08. The patentee bears the burden of proving that a nexus exists between the claimed features of the invention and the license taken out by the patentee's competitors, which, for reasons noted above, courts frequently find have not been met. *See, e.g.,*

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1539 (Fed. Cir. 1983); *In re GPAC*, 57 F.3d at 1580; *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d at 908.

g. ***Failure of Others***

If a party wishes to rely on the secondary consideration of failure of others to rebut a finding of nonobviousness, that party must produced evidence that other parties in the field tried and failed to achieve the patented invention. *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1275 (Fed. Cir. 1995). Absent a showing that others tried and failed to achieve the patented invention, "the mere passage of time without the claimed invention is not evidence of nonobviousness." *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004).

C. Whether the Asserted Claims of U.S. Patent No. 4,663,318 are Invalid for Lack of Enablement Under 35 U.S.C. § 112

A patent is invalid under 35 U.S.C. § 112 if the patent fails to enable one of ordinary skill in the art to make and use the claimed invention without engaging in undue experimentation. *Imperial Chem. Indus., PLC v. Danbury Pharmacal, Inc. v. Danbury Pharmacal, Inc.*, 777 F. Supp. 330, 374 (D. Del 1991), *aff'd*, 972 F.2d 1354 (Fed. Cir. 1992). "It is an applicant's obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file." *Application of Glass*, 492 F.2d 1228, 1232 (C.C.P.A. 1974).). Whether a disclosure in the specification sufficiently enables the claims is "determined from the viewpoint of persons of skill in the field of the invention *at the time the patent application was filed.*" *Ajinomoto Co., Inc. v. Archer Daniels Midland Co.*, 228 F.3d 1338, 1345 (Fed. Cir. 2000) (emphasis added).

The Federal Circuit has explained that "the how to use prong of *section 112* incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention."[2] *In re Cortwright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999). Like the broader enablement inquiry, utility must also be determined at the date of the patent application, not at some point down the road. *See Curtiss-Wright Corp. v. Link Aviation, Inc.*, 182 F. Supp. 106, 124 (N.D.N.Y. 1959) ("Utility must be determined as of the date of the invention. Present day requirements due to scientific advancement is not the test.").

In a case involving drugs for use in human therapy, the Federal Circuit in *Rasmusson v. SmithKline Beecham Corp.* reiterated the long-held principle that "'when there is a complete absence of data supporting statements which set forth the desired results of the claimed invention, the patent can be invalid under either section 112, paragraph 1 for lack of enablement or section 101 for lack of utility'." *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005) (quoting *In re Cortwright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999), quoting *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762 (Fed. Cir. 1984)).

In *Rasmusson*, the Court was confronted with an applicant who had provided no experimental data in support of his claimed method for treating prostate cancer with a chemical compound called finasteride. In upholding the Board's determination that the patent application at issue was not enabled, the Court held:

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[2] "'The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.' (Citation omitted). Consequently, it is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed. (Citation omitted)." *Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996). A specification must, therefore, describe the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same." *Id.* (citing 35 U.S.C. § 112).

> [W]here there is no indication that one skilled in [the] art ***would accept without question*** statements [as to the effects of the claimed drug products] and ***no evidence*** has been presented to demonstrate that the claimed products have those effects, an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement.

Id. at 1323 (citation omitted) (brackets in original) (emphasis added). In such a situation, the Court held that "substantiating evidence" is necessary "unless one with ordinary skill in the art would ***accept the allegations as obviously correct***" as of the time the patent application was filed. *Id.* (citation omitted) (emphasis added). Where one of ordinary skill in the art would not so accept the claimed invention, or would "doubt the objective truth of the statements contained therein which must be relied on for enabling support" and "no evidence has been presented to demonstrate that the claimed products do have those effects, an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement." *Id.* at 1324 (internal citation and quotation omitted).

The *Rasmusson* Court concluded by rejecting Rasmusson's assertion that the enablement requirement of § 112 requires only that the intended use of the patent is "not implausible." *Id.* at 1325. The Court stated:

> If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to 'inventions' consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses [**17] later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention ***rather than merely proposing an unproved hypothesis.***

Id. at 1325 (emphasis added). In other words, an "invention" claiming a method of treating a disease in humans using a particular drug is enabled only if, *in the absence of*

data, "one skilled in the art would accept without question statements" that the claimed method of using that drug actually treats the disease. *Id.* at 1323.

It is further axiomatic that "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." *Genentech, Inc. v. Novo Nordisk, A/S,* 108 F.3d 1361, 1366 (Fed. Cir. 1997). Indeed, in the context of the utility requirement of § 101, the Supreme Court has noted that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536 (1966).[3] Accordingly, there can be no enablement when "the teachings set forth in the specifications provide no more than a 'plan' or 'invitation' for those of skill in the art to experiment." *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374-75 (Fed. Cir. 1999). Therefore, Federal Circuit authority makes clear that to enable a patent that includes method of treatment claims using a particular drug, the patentee must provide credible evidence of utility.

In addition, to be enabled, a patent specification must also teach those skilled in the art to make and use the full scope of the claimed invention without undue experimentation. *Durel Corp. v. Osram Sylvania, Inc.*, 256 F.3d 1298, 1306 (Fed. Cir. 2001). If the patent specification does not provide sufficient guidance to allow one of ordinary skill in the art to practice the full scope of the invention without "undue

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[3] This is further supported by Federal Circuit's precedent with respect to the issue of conception. "The difficulty that would arise if we were to hold that a conception occurs when one has only the idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, ***which is to promote disclosure of inventions, not of research plans.***" *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993) (emphasis added). *See also Northpoint Tech. v. MDS Am.*, 413 F.3d 1301, 1310 (Fed. Cir. 2005) ("There is no enablement when the teachings set forth in the specifications provide no more than a plan or invitation for those of skill in the art to experiment").

experimentation," the patent is not enabled, and is therefore invalid. *Imperial Chem.*, 777 F. Supp. at 373. A determination as to whether undue experimentation is necessary "is not a single simple factual determination, but rather a conclusion reached by weighing many factual considerations." *Id.*. at 373. These considerations include: 1) the quantity of experimentation necessary; 2) the amount of the direction or guidance presented; 3) the presence or absence of working examples;[4] 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F. 3d 1326, 1337 (Fed. Cir. 2005). Where reasonable guidance is not provided, thus making necessary, for example, extensive studies to determine an effective dose range, the amount of experimentation would be considered undue and the invention would not be enabled. *Imperial Chem.*, 777 F. Supp. at 374.

The enablement requirement demands that the patent specification enable those skilled in the art to make and use the invention as broadly as it is claimed. *Glaxo Wellcome, Inc. v. Eons Labs Mfg., Inc.*, No. 00-CIV-9089, 2002 U.S. Dist. LEXIS 14950 at *6 (S.D.N.Y., August 13, 2002). A patent application is not enabled if one of ordinary skill would not have been able to produce the invention at the time of the application. *Biotechology General Corp. v. Novo Nordisk A/C*, 2004 U.S. Dist. LEXIS 14959 * 63 (D.Del. 2004)("a plaintiff's own failures to make and use the claimed invention at the time of the patent application supports a finding of nonenablement."). The Federal

[4] The lack of a working example is a factor to be considered when determining whether an application complies with the enablement requirement of 35 U.S.C. §112, especially in a case involving an unpredictable and undeveloped art. *Bio-Technology Gen. Corp. v. Novo Nordisk Pharms., Inc.*, No. 02-235-SLR, 2004 WL 1739722 (D. Del. August 3, 2004) (citing United States Patent and Trademark Office, United States Department of Commerce, Manual of Patent Examining Procedure § 2164.02).

Circuit has highlighted the significance of unpredictability in evaluating the validity of broad claims, particularly in "unpredictable art areas [such as the chemical arts]" where courts "refuse[] to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claims." *PPG Indus. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

A pharmaceutical patent with an exceedingly broad dose range disclosure, combined with no data offered in support of such a broad disclosure, or guidance on how to practice the claimed invention across the full range of the claim, does not meet the requirement of an adequate disclosure required by 35 U.S.C. § 112. *See Imperial Chem.*, 777 F. Supp. at 373-375 (holding that a method patent on atenolol, with a dose range disclosure of 25-1200 mg of atenolol, was not enabled due to the breadth of the range, lack of data supporting efficacy in the entire range, and the fact that several years of dose studies had to be conducted with atenolol to determine its ultimate, much lower, effective range). In such instance, a claimed invention is not enabled. *Id.* at 374.

Tab 6

PLAINTIFFS' PRE-MARKED TRIAL EXHIBITS [REDACTED]

Tab 7

DEFENDANTS' PRE-MARKED TRIAL EXHIBITS [REDACTED]

Tab 8

PLAINTIFFS' WITNESS LIST

Plaintiffs expect that they may call the following witness to testify at trial. To the extent permitted by the Federal Rules of Evidence and the Federal Rules of Civil Procedure, Plaintiffs reserve the right to introduce the prior sworn testimony of any witness identified below:

Fact Witnesses

Magid Abou-Gharbia

REDACTED

Seshu Akula
Dr. Reddy's Laboratories, Inc.
200 Somerset Corporate Center
Bridgewater, New Jersey 08807

Joanne Berger-Sweeney
Wellesley College
106 Central Street
Wellesley, MA 02481

Paul Bisaro

REDACTED

Cheryl Blume
Pharmaceutical Development Group
13902 North Dale Mabry Highway, Suite 122
Tampa, Florida

Paul Campenelli
Par Pharmaceuticals, Inc.
300 Tice Boulevard
Woodcliff Lake, New Jersey

Joseph Coyle
Harvard University Medical School
McLean Hospital, MRC
115 Mill Street
Belmont, MA 02478

Jeffrey Cummings
Department of Neurology
University of California, Los Angeles
710 Westwood Plaza, Suite 2-238
Los Angeles, CA 90095-1769

Bonnie Davis

REDACTED

Charles DiLiberti
Barr Laboratories, Inc.
400 Chestnut Ridge Road
Woodcliff Lakes, New Jersey

Josephine Dundon
Actavis, Inc.
14 Commerce Drive
Cranford, New Jersey

Howard Fillit
Alzheimer's Drug Discovery Foundation
1414 Avenue of the Americas, Suite 1502
New York, NY 10019

Melissa Goodhead
Somerset Pharmaceuticals, Inc.
2202 North West Shore Boulevard, Suite 450
Tampa, Florida 33607

Jason Harper
Mylan Pharmaceuticals, Inc.
781 Chestnut Ridge Road
Morgantown, West Virginia 26505

Deborah Jaskot
Teva Pharmaceuticals USA, Inc.
1090 Horsham Road
North Wales, Pennsylvania 19454

Karen Kauffman
University of Maryland, School of Nursing
Room 655A
655 West Lombard Street
Baltimore, MD 21201

Tina Kaufman
Johnson & Johnson
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Gary King

REDACTED

Paul Krauthauser
Teva Pharmaceuticals USA, Inc.
1090 Horsham Road
North Wales, PA 19454

Anne Payne
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1090 Horsham Road
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University of Washington School of Medicine
1660 S. Columbian Way
Seattle, WA 98108

Brian Roman
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781 Chestnut Ridge Road
Morgantown, West Virginia, 26505

Howard Rosenberg

REDACTED

Timothy Sawyer
Barr Laboratories, Inc.
400 Chestnut Ridge Road
Woodcliff Lake, New Jersey

Barry Spencer

REDACTED

Luc Truyen
Johnson & Johnson
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Expert Witnesses

Joseph Coyle

Dr. Joseph Coyle is an expert neuropsychopharmacologist and professor of psychiatry and neuroscience at Harvard University School of Medicine whose research has focused, among other things, on the development and use of animal models for the testing of drugs for neurological disorders, including Alzheimer's Disease. Dr. Coyle will testify about the neurochemistry of Alzheimer's Disease and the history and state of the art at the time of the invention of the neurochemical understanding of the disease, as well as the perspective of a neuropsychopharmacologist about the nonobviousness of the invention of the '318 Patent, including as to the objective indicia of skepticism, long-felt need, failure of others, and unexpected benefits. In addition, Dr. Coyle will testify on the subject of whether one of ordinary skill in the art at the time that the application which led to the '318 Patent was filed would be enabled to make and use the invention, and whether the '318 Patent provides sufficient written description to demonstrate that Dr. Davis was in possession of a useful invention at the time the application was filed. Dr. Coyle will also testify about the testing in animals that was conducted in his laboratory that provided further confirmation that the patented invention works for its intended purpose. Dr. Coyle's opinions are set forth in more detail in his expert reports, and he reserves the right to testify as to any opinions set forth therein or discussed during his deposition in this matter, and he will also respond to assertions made by Defendants' experts on the same subjects.

Jeffrey Cummings

Dr. Jeffrey Cummings is a clinical psychiatrist and professor at the University of California, Los Angeles School of Medicine whose research has focused, among other things, on the treatment of neurological disorders, particularly the neuropsychiatric syndromes associated with neurological disorders such as Alzheimer's disease. For example, Dr. Cummings is one of the creators of the "Neuropsychiatric Index" or "NPI" that is widely used to assess the non-cognitive symptoms of neurological disorders including Alzheimer's disease and to evaluate the effects of drugs on those symptoms. Dr. Cummings will testify about the non-cognitive symptoms of Alzheimer's Disease, about the history and state of the art of attempts to treat the disease and, from the perspective of a clinician and researcher with expertise in diagnosing Alzheimer's disease and characterizing its behavioral aspects, about the nonobviousness of the invention of the '318 Patent, including as to the objective indicia of skepticism, long-felt need, failure of others, and unexpected benefits. In addition, Dr. Cummings will testify on the subject of whether one of ordinary skill in the art at the time that the application which led to the '318 Patent was filed would be enabled to make and use the invention, and whether the '318 Patent provides sufficient written description to demonstrate that Dr. Davis was in possession of a useful invention at the time the application was filed. Dr. Cummings's opinions are set forth in more detail in his expert reports, and he reserves the right to testify as to any opinions set forth therein or discussed during his deposition in this matter, and he will also respond to assertions made by Defendants' experts on the same subjects.

Howard Fillit

Dr. Howard Fillit is an expert in the field of discovery and development of treatments for Alzheimer's disease. Dr. Fillit is the Executive Director of the Institute for the Study of Aging and the Alzheimer's Drug Discovery Foundation, a professor of geriatrics and medicine at Mt. Sinai, and an associate physician at Rockefeller University Hospital. Dr. Fillit's research has focused on the identification and evaluation of drug candidates for Alzheimer's disease. He will testify from the perspective of a drug development expert about the nonobviousness of the invention of the '318 Patent, including as to the objective indicia of failure of others, skepticism, long-felt need, and unexpected benefits. In addition, Dr. Fillit will testify on the subject of whether one of ordinary skill in the art at the time that the application which led to the '318 Patent was filed would be enabled to make and use the invention, and whether the '318 Patent provides sufficient written description to demonstrate that Dr. Davis was in possession of a useful invention at the time the application was filed. Dr. Fillit's opinions are set forth in more detail in his expert reports, and he reserves the right to testify as to any opinions set forth therein or discussed during his deposition in this matter, and he will also respond to assertions made by Defendants' experts on the same subjects.

Karen Kauffman

Dr. Karen Kauffman is an expert in the field of nursing with particular expertise in the caregiver burden associated with Alzheimer's disease. Dr. Kauffman will testify from the perspective of a nurse about the nonobviousness of the invention of the '318 Patent, including as to the objective indicia of long-felt need and failure of others. Dr. Kaufman's opinions are set forth in more detail in her expert reports, and she reserves the right to testify as to any opinions

set forth therein or discussed during her deposition in this matter, and she will also respond to assertions made by Defendants' experts on the same subjects.

Tina Kaufman

Ms. Tina Kaufman is an expert in the field of pharmaceutical sales and marketing, and she will testify from that perspective about the nonobviousness of the invention of the '318 Patent, and particularly as to the objective indicia of commercial success. Ms. Kaufman's opinions are set forth in more detail in her expert report, and she reserves the right to testify as to any opinions set forth therein or discussed during her deposition in this matter, and she will also respond to assertions made by Defendants' experts on the same subjects.

Louis Morris

Dr. Louis Morris is an expert in regulatory issues associated with the U.S. Food & Drug Administration ("FDA"), and particularly FDA's Division of Drug Marketing and Communications ("DDMAC"). Dr. Morris will testify as to the nonobviousness of the invention of the '318 Patent, and particularly as to the objective indicia of unexpected benefits as reflected by Plaintiffs' communications with DDMAC concerning the RAZADYNE product. Dr. Morris's opinions are set forth in more detail in his expert reports, and he reserves the right to testify as to any opinions set forth therein or discussed during his deposition in this matter, and he will also respond to assertions made by Defendants' experts on the same subjects.

Murray Raskind

Dr. Murray Raskind is psychiatrist who is the Executive Director of the Department of Veterans Affairs Puget Sound Mental Health Services, a Professor of Psychiatry and the University of Washington School of Medicine, and the Director of the University of Washington Alzheimer's Disease Research Center. Dr. Raskind's practice and research has focused on the development and use of drugs for the treatment of neurological disorders, including Alzheimer's disease, and he is a principal investigator in an on-going trial studying the long-term effects of galantamine hydrobromide in the treatment of Alzheimer's disease. Dr. Raskind will testify about the clinical manifestations of Alzheimer's disease, the history and state of the art at the time of the invention of attempts to treat Alzheimer' disease, as well as, from the perspective of a clinician with vast experience treating Alzheimer's patients, about the nonobviousness of the invention of the '318 Patent, including as to the objective indicia of skepticism, long-felt need, failure of others, and unexpected benefits. Dr. Raskind is also expected to testify as to his personal involvement in developing Alzheimer's treatment drugs, and his failure to do so successfully (as well as the failures of many others to do so successfully). In addition, Dr. Raskind will testify on the subject of whether one of ordinary skill in the art at the time that the application which led to the '318 Patent was filed would be enabled to make and use the invention, and whether the '318 Patent provides sufficient written description to demonstrate that Dr. Davis was in possession of a useful invention at the time the application was filed. Dr. Raskind's opinions are set forth in more detail in his expert reports, and he reserves the right to testify as to any opinions set forth therein or discussed during his deposition in this matter, and he will also respond to assertions made by Defendants' experts on the same subjects.

Marion Stewart

Dr. Marion Stewart is an economist, professor of economics, and consultant who will testify as to the nonobviousness of the invention claimed by the '318 Patent, and particularly as to the objective indicia of the commercial success of Plaintiffs' RAZADYNE product. Dr. Stewart's opinions are set forth in more detail in his expert reports, and he reserves the right to testify as to any opinions set forth therein or discussed during his deposition in this matter, and he will also respond to assertions made by Defendants' experts on the same subjects.

* * *

By identifying these witnesses, Plaintiffs are not required to call them at trial, nor are Plaintiffs limited in the manner in which such testimony is to be presented at trial. In addition, Plaintiffs reserve the right to call as witnesses at trial: (1) any additional witness to provide foundational testimony should Defendants contest the authenticity or admissibility of any materials to be proffered at trial; (2) any witness identified by Plaintiffs on their trial witness lists; (3) any substitute witnesses, to the extent that the employment of any of the above individuals changes or in the event that they otherwise become unavailable for trial; (4) any additional witnesses to respond to issues raised after the submission of this list, such as testimony of witnesses who have not yet been identified and/or deposed; and (5) any additional witness for purposes of impeachment.

Tab 9

EXHIBIT 9

WITNESSES DEFENDANTS MAY CALL AT TRIAL

Defendants set forth below the names and addresses of the witnesses whom Defendants intend to call to testify in their case-in-chief at trial. If any witness listed as a person who Defendants intend to call to testify in person is unable to testify live at trial for health reasons, Defendants reserve the right to offer deposition testimony from such witness. The listing of a witness does not require Defendants to call that witness to testify, either in person or by deposition.

Name of Witness	**Address of Witness**	**Live or by Deposition**	**Field of Specialty (If testifying as expert witness.)**
Dr. Allan I. Levey,	Emory Univ. School of Medicine Whitehead Medical Research Building 505 615 Michael Street Atlanta, GA 30322	Live or Deposition	Various theories concerning the issues of invalidity, including the secondary considerations of non-obviousness and the opinions expressed in Dr. Levey's expert reports.
Dr. Edward F. Domino	REDACTED	Live or Deposition	Various theories concerning the issues of invalidity, including the secondary considerations of non-obviousness and the opinions expressed in Dr. Domino's expert reports.
Harry C. Boghigian	REDACTED	Live or Deposition	Financial aspects – sales/marketing of pharmaceutical products, commercial success and the opinions expressed in Mr. Boghigian's expert report.
Dr. Howard Rosenberg,	Generics UK Albany Gate Darkes Lane Potters Bar Hertfordshire 1AG United Kingdom	Live or Deposition	
Paul Bisaro	400 Chestnut Ridge Rd. Woodcliff Lake, NJ	Live or Deposition	
Dr. Kenneth Davis	REDACTED	Live or Deposition	

Dr. Bonnie Davis	REDACTED	Live or Deposition	
Dr. Michael Rainer	Austria	Live or Deposition	
Dr. Murray Raskind	REDACTED	Live or Deposition	Various theories concerning the issues of invalidity, including the secondary considerations of non-obviousness and the opinions expressed in Dr. Raskind's expert reports.
Dr. Jeffrey Cummings	Department on Neurology University of California Los Angeles 710 Westwood Plaza, Suite 2-238 Los Angeles CA 90095-1769	Live or Deposition	Various theories concerning the issues of invalidity, including the secondary considerations of non-obviousness and the opinions expressed in Dr. Cummings' expert reports.
Dr. Howard Fillit	REDACTED	Live or Deposition	Various theories concerning the issues of invalidity, including the secondary considerations of non-obviousness and the opinions expressed in Dr. Fillit's expert reports.
Dr. Joseph T. Coyle	REDACTED	Live or Deposition	Various theories concerning the issues of invalidity, including the secondary considerations of non-obviousness and the opinions expressed in Dr. Coyle's expert reports.

Tab 10

PLAINTIFFS' BRIEF STATEMENT OF INTENDED PROOFS

Plaintiffs will prove the following at trial:

I. INFRINGEMENT [STIPULATED]

A. Defendants have infringed claim 1 and 4 of the '318 Patent, either literally or under the doctrine of equivalents, by making, using, or seeking to offer for commercial use or sale a generic version of Plaintiffs' RAZADYNE product, the commercial embodiment of the '318 Patent.

B. Defendants do not contest infringement.

II. VALIDITY

A. Defendants have failed to overcome the presumption of patent validity and prove by clear and convincing evidence that claims 1 and 4 of the '318 Patent are invalid.

B. Anticipation: Defendants have failed to prove by clear and convincing evidence that claims 1 and 4 of the '318 Patent are invalid over the prior art as anticipated.

1. Defendants have failed to prove by clear and convincing evidence that *Bhasker*, either expressly or inherently, each and every element of claim 1 of the '318 Patent.

2. Defendants have failed to prove by clear and convincing evidence that *Bhasker* constitutes a single printed publication.

3. Defendants have failed to show by clear and convincing evidence that *Bhasker* would enable a person of ordinary skill in the art to make and use the invention claimed in the '318 Patent.

C. Obviousness: Defendants have failed to prove by clear and convincing evidence that the invention described in claims 1 and 4 of the '318 Patent is invalid over the prior art as obvious.

1. A person of ordinary skill in the art would be a medical physician treating elderly individuals with Alzheimer's disease as of January 15, 1986.

2. Defendants have failed to prove that the '318 Patent was obvious to a person of ordinary skill in the art at the time of the claimed invention that galantamine would work as a treatment for Alzheimer's disease in light of the scope and content of the prior art and the differences between claims 1 and 4 of the '318 Patent and the prior art.

3. Defendants have failed to prove by clear and convincing evidence that there is a suggestion, motivation, or teaching in the prior art references that would have led a person of ordinary skill in the art to select the references for combination.

4. Defendants have failed to prove by clear and convincing evidence that a person of ordinary skill in the art would have been motivated to combine the teachings of prior art references to discover that galantamine would work as a treatment for Alzheimer's disease.

5. Defendants have failed to prove by clear and convincing evidence that a person of ordinary skill in the art had a reasonable expectation of success that galantamine would work as a treatment for Alzheimer's disease.

6. Objective Indicia of Nonobviousness: In rebutting Defendants' allegations of obviousness, Plaintiffs will introduce evidence that:

   i. There was a long felt but unmet need for a treatment for Alzheimer's disease, and the '318 Patent satisfied that long felt need;

   ii. Before and after the filing of the application that became the '318 Patent, other inventors attempted to develop a treatment for Alzheimer's disease yet failed;

   iii. Before and after the '318 Patent, those skilled in the art were skeptical that galantamine would work as a treatment for Alzheimer's disease;

   iv. The '318 Patent has achieved recognition in the industry including licensing, copying, and acquiescence;

   v. The '318 Patent has produced unexpected results; and

   vi. The RAZADYNE product – the commercial embodiment of the '318 Patent – is a commercial success and there is a nexus between the invention and any commercial success.

D. Enablement: Defendants have failed to prove by clear and convincing evidence that claims 1 and 4 of the '318 Patent are invalid for failure to comply with the enablement requirement of 35 U.S.C. § 112.

E. Written description: Defendants have failed to prove by clear and convincing evidence that claim 4 of the '318 Patent is invalid for failure to comply with the written description requirement of 35 U.S.C. § 112.

III. RELIEF AGAINST DEFENDANTS

A. Whether Plaintiffs are entitled to a permanent injunction against Defendants and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the galantamine hydrobromide tablets for which approval is sought in Defendants' ANDAs, or any galantamine hydrobromide product that infringes or induces or contributes to the infringement of the '318 Patent, until expiration of that patent.

B. Whether Plaintiffs are entitled to an order under 35 U.S.C.§ 271(e)(4) ordering that Defendants' ANDAs for galantamine hydrobromide tablets not be approved until the expiration of the '318 Patent and any associated exclusivity period.

C. Whether this is an exceptional case, finding appropriate an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285.

D. The appropriate award of Plaintiffs' costs and expenses in this action.

Tab 11

DEFENDANTS' BRIEF STATEMENT OF INTENDED PROOFS

Dr. Bonnie Davis claims to have invented the use of galanthamine as a method of treating Alzheimer's disease. The simple fact of the matter is that Dr. Davis' patent did nothing to advance the art of treating Alzheimer's disease. Her "invention" was anticipated by a journal article in 1974, and in any event was obvious to those skilled in the art and *was reasonably expected* to work based on the prior art at the time that the application was filed. Her patent does not advance the art and show that the invention *actually* would work, as is necessary under the enablement requirement.

The Janssen Plaintiffs sell galanthamine under the trade name Razadyne®, formerly known and sold as Reminyl®. The Defendants in this case, Barr Pharmaceuticals, Inc., Barr Laboratories, Inc. and Alphapharm Pty., Ltd. (hereinafter "Defendants"), are pharmaceutical companies that seek U.S. FDA approval to market a generic version of the drug galanthamine for the treatment of Alzheimer's disease. Plaintiffs sued the Defendants for patent infringement under the Hatch Waxman Act on United States Patent No. 4,663,318 (the "'318 patent"), which claims the administration of galanthamine as a method of treating Alzheimer's disease and related dementias. Defendants do not contest infringement.

Defendants assert the following defenses against the '318 patent:

1. The asserted claims of the '318 patent are invalid because they are anticipated under 35 U.S.C. § 102(b) by P.A. Bhasker's 1974 article entitled "Medical Management of Dementia."

2. The asserted claims of the '318 patent are invalid because they are obvious over the prior art under 35 U.S.C. § 103.

3. The asserted claims of the '318 patent are invalid for lack of enablement under 35 U.S.C. § 112.

I. THE ASSERTED CLAIMS OF THE '318 PATENT ARE INVALID BECAUSE THEY ARE ANTICIPATED UNDER 35 U.S.C. §102(b) BY P.A. BHASKER'S 1974 ARTICLE ENTITLED "MEDICAL MANAGEMENT OF DEMENTIA"

The asserted claims of the '318 patent are invalid because they are anticipated under 35 U.S.C. § 102(b) by P.A. Bhasker's article "Medical Management of Dementia." *The Antiseptic*, Vol. 71 No. 1 pp. 47 (1974). Bhasker describes the treatment of "progressive," "irreversible dementias" generally, which necessarily includes the most prevalent of the irreversible dementias, Alzheimer's disease, even though the article does not mention Alzheimer's disease by name. Bhasker describes these dementias as characterized by "a progressive fall-out of neurons and [where] the course of the illness is rapidly downhill." One of ordinary skill in the art in 1986 would have understood that patients with Alzheimer's disease would be encompassed by those who experience such a "progressive fall-out of neurons" where the course of the illness can be rapidly downhill.

Furthermore, Bhasker discusses the treatment of such progressive, irreversible dementias through many avenues, including the use of drugs, traditional care-giving, and even surgery. Bhasker's discussion of the treatment of such dementias is done in terms of "the restoration of higher cortical functions," such as speech and memory, the diminution of which has long been recognized as a prominent symptom of Alzheimer's disease. This "restoration of higher cortical functions" is described by Bhasker as being accomplished through "deinhibition," which Bhasker defines as "the facilitation of acetylcholine activity by giving small daily doses of Cholinesterase inhibitors (Neostigmine, Gallanthamine, etc.)." Defendants assert that one of ordinary skill in the art in 1986 reading Bhasker would have understood the article as disclosing a method of treating dementias, including Alzheimer's disease, by administering a

therapeutically effective amount of galanthamine to a patient suffering from such a disease.

II. THE ASSERTED CLAIMS OF THE '318 PATENT ARE INVALID BECAUSE THEY ARE OBVIOUS OVER THE PRIOR ART UNDER 35 U.S.C. 103

A. The Use of Galanthamine to Treat Alzheimer's Disease Was Obvious

The asserted claims of the '318 patent are also invalid for obviousness under 35 U.S.C. § 103. The evidence at trial will show that as of 1986, the prior art clearly taught that there was a loss of the neurotransmitter acetylcholine (*i.e.*, a cholinergic deficit) in the brains of individuals stricken by Alzheimer's disease. Furthermore, the prior art also taught that acetylcholine was very important in memory, and that drugs that could slow or prevent the loss of acetylcholine in the brain could be effective in treating the memory loss associated with Alzheimer's disease. These findings were the basis for what became known as the cholinergic deficit hypothesis.

This cholinergic deficit hypothesis led to three approaches in dealing with the acetylcholine loss and thus attempting to treat Alzheimer's disease: the presynaptic, the intrasynaptic, and the postsynaptic approaches. Acetylcholinesterase breaks down acetylcholine and thus acetylcholinesterase inhibitors inhibit the breakdown of acetylcholine. The intrasynaptic approach utilized reversible acetylcholinesterase inhibitors that cross the blood-brain barrier – a limited class of drugs that includes physostigmine, tacrine, *and galanthamine* – to treat Alzheimer's disease. Unlike the presynaptic and postsynaptic approaches, the intrasynaptic approach was the only approach with proof of concept in humans prior to January 15, 1986, when Dr. Davis applied for her patent. That is, using reversible acetylcholinesterase inhibitors (namely, tacrine and physostigmine) had been proven in humans (and reported in the literature) to

be effective in treating cognitive symptoms of Alzheimer's disease prior to 1986. Indeed, most of the prior art on physostigmine had been authored by Dr. Bonnie Davis' husband, Dr. Ken Davis. Both physostigmine and tacrine had drawbacks, however, including a relatively short duration of action and a less than desirable side effect profile. It was obvious in 1986 to one of ordinary skill in the art reading the literature that the ideal drug candidate for treating Alzheimer's disease would perform like these two drugs, without the drawbacks.

By 1986, it was well known to those of ordinary skill in the art that galanthamine was just such an ideal drug candidate. Bhasker, to the extent it is not found to be anticipating, clearly sets forth galanthamine as a compound to use to treat dementias such as Alzheimer's disease. Moreover, it was well known prior to 1986 that galanthamine's mechanism of action was through acetylcholinesterase inhibition, that galanthamine was a strong reversible acetylcholinesterase inhibitor that crossed the blood-brain barrier, and that galanthamine was longer lasting than and had other benefits over physostigmine and tacrine. Specifically, galanthamine was longer acting, had less toxicity, and a larger therapeutic range than physostigmine. In addition, it was well known in the art that galanthamine is one of the only other types of cholinesterase inhibitors that crossed the blood-brain barrier because it was a tertiary amine like physostigmine and had the same mechanism of action as physostigmine.

Furthermore, galanthamine was not a novel compound in 1986, having been sold in Europe to treat a variety of central nervous system disorders prior to the filing of the application that led to the '318 patent. Its history in the literature dates back more than 40 years. Indeed, the '318 patent itself recognizes that galanthamine was well-

known in the art to have anticholinesterase properties, and that it had been used safely and effectively in humans for years. In light of this volume of knowledge, and the voluminous prior art that will be the subject of expert testimony at trial, the use of galanthamine for the treatment of Alzheimer's disease was obvious to one skilled in the art when Dr. Bonnie Davis filed her patent application on January 15, 1986.

Further proof of the obviousness of Bonnie Davis' "invention" is that by at least 1986,

REDACTED

B. There Are No Persuasive Secondary Considerations of Nonobviousness

None of the secondary considerations relied on by Plaintiffs rebuts a finding of obviousness in this case. For example, the alleged commercial success of Reminyl/Razadyne - the commercial embodiment of the '318 patent - simply does not establish that galanthamine was not obvious.

REDACTED

Next, Plaintiff's "proof" of "unexpected benefits" of galanthamine does not establish non-obviousness.

REDACTED

"[I]t is well settled that unexpected results must be established by factual evidence. 'Mere argument or conclusory statements . . . does not suffice.'" *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997) (citation omitted).

Furthermore, any evidence of the secondary consideration of copying is irrelevant in this case. In the specific area of patent law relating to generic drug companies and the ANDA process, copying "is what generic drug companies do. That is why their products are cheaper." *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, No. 2:05CV421, 2006 WL 2008962, at *45 (E.D. Va. July 16, 2006) (citing Walker on Patents). In the ANDA context, "given that there is a statute in place that encourages generic drug companies to challenge patents . . . [a] copying argument is weak." *Id.* at *45. Simply put, the copying done by generic drug companies in the context of Hatch Waxman proceedings establishes only that others believe that the patents are invalid and should be challenged.

Next, Plaintiffs cannot present evidence of long-felt, but unmet need since Reminyl was the fourth drug in the same class approved for the treatment of Alzheimer's disease. A "long-felt" need is not present where there are already several other effective drugs of the same class in the marketplace. *See Aventis Pharma Deutschland GMBH v. Lupin, Ltd.*, 2006 WL 2008962, No. 2:05CV421, slip op. at *45 (E.D. Va. July 17, 2006)

(finding that there "simply was no 'long-felt need'" for a drug where there were already "several effective" drugs of the same class already on the market).

Finally, any purported evidence that Plaintiffs may attempt to introduce of "licensing" and "failure of others" is not of sufficient weight to rebut a finding that the '318 patent is obvious. Therefore, as Plaintiffs can provide no persuasive secondary considerations of nonobviousness, a finding that the '318 patent is obvious should stand.

III. THE ASSERTED CLAIMS OF THE '318 PATENT ARE INVALID FOR LACK OF ENABLEMENT UNDER 35 U.S.C. § 112

The asserted claims of the '318 patent are invalid for lack of enablement under 35 U.S.C. § 112. Defendants assert that the '318 patent was not enabled for two reasons: 1) contrary to the requirements of enablement related to drug products as set forth in *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005), Bonnie Davis did not provide *any* data in her patent application to support the claimed effects of her alleged invention – she merely proposed an unproven hypothesis; and 2) the full scope of Claim 4 of the '318 patent is not enabled and thus the entire claim is invalid.

A. The '318 Patent is not enabled under *Rasmusson*

The Federal Circuit's recent decision in *Rasmusson* reaffirmed the principle that a patent applicant cannot merely propose an unproved hypothesis and be rewarded with a patent, even if the patent applicant's guess turns out to be correct. *Rasmusson,* 413 F.3d at 1323. In the context of drugs for human therapy, *Rasmusson* held that unless one skilled in the art would "accept without question" the patent applicant's claims, a patent applicant must present evidence that his or her claimed product or method has the effects claimed. *Id.* Failure to provide such evidence will result in a patent being invalid for lack of enablement. Indeed, the policy behind the U.S.

patent law "is to promote disclosure of inventions, not of research plans." *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993); *see also Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994) (stating that an inventor must have a "specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue."); *Application of Glass*, 492 F.2d 1228, 1232 (C.C.P.A. 1974). ("It is an applicant's obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file.").

In her patent application, Dr. Davis proposed exactly the sort of "unproved hypothesis" prohibited by *Rasmusson*.

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There is no evidence that anyone in the United States, as of January 15, 1986, had done any testing of galanthamine that provided data demonstrating or suggesting galanthamine's effectiveness in treating patients with Alzheimer's disease.

Furthermore, the '318 patent itself does not provide sufficient evidence to demonstrate that the proposed invention would have the claimed effects. The patent does

nothing more than cite several pieces of disparate prior art, and provide reference to an animal model which it claims "provides a good animal model for Alzheimer's disease in humans." ('318 patent, 2:45-46). The model referenced, however, was used with physostigmine, REDACTED

Rather, the '318 patent provided only an unproven hypothesis, for which the work of establishing *any* efficacy (in animals or humans) was yet to be done.

In addition to the lack of data or evidence in the '318 patent specification confirming that the alleged invention had the claimed effects, there is nothing in the prior art to show that one of ordinary skill in the art would have "accepted without question" that galanthamine would be a therapeutically effective treatment for Alzheimer's disease. Lacking this or any data demonstrating that galanthamine would work as a method of treating Alzheimer's disease, the patent fails to meet the enablement requirement.

B. The Full Scope of Claim 4 of the '318 Patent Is Not Enabled

Claim 4 of the '318 patent claims that a dosage range of 10-2000 milligrams of galanthamine per day represents a "therapeutically effective" treatment for Alzheimer's disease. As noted above, Bonnie Davis provided no information in the '318 patent that galanthamine had ever been used to treat Alzheimer's disease, nor did she provide any data – animal or otherwise – *even suggesting* that galanthamine would be therapeutically effective *at any dose range*, let alone from as low as 10 milligrams to as high as 2000 milligrams. This is an enormous dose range. While it is doubtful that 10 milligrams of galanthamine could be therapeutically effective to treat Alzheimer's disease, there is not a shred of evidence

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It is black letter law that a patent specification must enable the full scope of a claimed invention, especially so in areas of unpredictable arts, including the chemical arts. *PPG Indus., Inc. v. Guardian Indus., Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996). A pharmaceutical patent with an exceedingly broad dose range disclosure, combined with no data offered in support of such a broad disclosure, or guidance on how to practice the claimed invention, does not meet the requirement of an adequate disclosure required by 35 U.S.C. § 112. *See Imperial Chem. Indus., PLC v. Danbury Pharmacal, Inc. v. Danbury Pharmacal, Inc.*, 777 F. Supp. 330, 373-375 (D. Del 1991), *aff'd*, 972 F.2d 1354 (Fed. Cir. 1992) (holding that a method patent on atenolol, with a dose range disclosure of 25-1200 mg of atenolol, was not enabled due to the breadth of the range, lack of data supporting efficacy in the entire range, and the fact that several years of dose studies had to be conducted with atenolol to determine its ultimate, much lower, effective range). In such instance, a claimed invention is not enabled. *Id.* at 374. Therefore, the full scope of Claim 4 of the '318 patent was not enabled, and thus is invalid in its entirety.

Tab 12

PLAINTIFFS' LIST OF MISCELLANEOUS ISSUES

- Trial schedule and organization;
- Order of proof at trial;
- Claim construction;
- Treatment of "Confidential" or "Highly Confidential" documents and information at trial;
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REDACTED

- Standing of the Defendant, Barr Pharmaceuticals, Inc.

Tab 13

EXHIBIT 13

DEFENDANTS' MISCELLANEOUS ISSUES FOR THE PRETRIAL CONFERENCE

Defendants intend to raise the following issues at the Pretrial Conference:

1. Whether the Court will exclude or limit the testimony of Plaintiffs' medical experts Drs. Coyle, Cummings, Raskind and Fillit and Karen Kauffman, Ph.D. because their testimony is redundant, duplicative and/or irrelevant.

2. REDACTED

3. Whether Barr Pharmaceuticals, Inc. should be dismissed as a party because Barr Pharmaceuticals, Inc. did not file the ANDA at issue in this litigation.

4. Resolution of Pretrial Order disagreements.

5. Scheduling of trial (*i.e.,* trial calendar, length of trial, amount of time per side, whether there will be closing arguments, how the Court will handle objections to trial exhibits, how the parties will move exhibits into evidence).

6. Order of proof.

7. How the Court will handle translations and the admissibility of foreign language documents.

8. Whether the Court will permit amendment to the Pretrial Order prior to trial if, as expected, the parties reach further agreement regarding facts not in dispute.

9. Access to courtroom/wiring, *etc.*

10. Procedure for ordering daily transcripts.